

2016

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Recommended Citation

Oumer, Elham, "Is Acupuncture an Effective Treatment for Women With Chronic Migraine?" (2016). *PCOM Physician Assistant Studies Student Scholarship*. 293.

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Is Acupuncture An Effective Treatment For women with Chronic Migraine?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences-Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

December 18, 2015

ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not acupuncture is effective in treating chronic migraine in women between the ages of 18-65.

STUDY DESIGN: Review of two randomized controlled trials and one prospective controlled trial published in English language between 2009 and 2014.

DATA SOURCES: Two RCTs and one prospective CT published in peer reviewed journals, searched through PubMed, EBSCOhost.

OUTCOMES MEASURED: The outcome measured included improvement in quality of life, reduction in intensity and number of headache days. This were measured using 50% responders analysis, self reporting by participants, short form 36 (SF-36) and MIDAS index.

RESULTS: Facco et al treatment which showed significant improvement in patient daily activity and number of headache days after treatment with acupuncture compared to valproic acid. Ferro et al showed significant improvement in social functioning and quality of life following acupuncture treatment compared to TAN. Yang et al showed significant decreased in number of headaches days after treatment with traditional acupuncture compared with topiramate therapy.

CONCLUSION: This review shows that the use of acupuncture is an effective way to treat chronic migraine or decrease the severity of it. In addition, the lack of side effect and low number needed to treat (NNT) makes acupuncture an effective treatment. More is research is on the way to look at the long term effect of using acupuncture treatment.

KEY WORDS: Chronic Migraine, Acupuncture

INTRODUCTION

Headache is one the most devastating and common problem of the nervous system. There are different types of headaches and chronic migraine has become a common diagnosis and a growing problem.¹ Migraine is a disabling phenomenon that interrupts a person's activity of daily living. Migraine in general is also called episodic migraine because patients can go weeks or months without having an episode. However chronic migraine is a throbbing, unilateral headache associated with nausea, vomiting, sensitivity to light or sound.^{2,3} People with chronic migraine have episodes more than 15days per month. The pathogenesis of migraine is not differentiated exactly, however its thought to be due to the malfunction of monoaminergic sensory control system within the brainstem and hypothalamus.² This paper evaluates two randomized controlled trials and one prospective control trial comparing the effect of acupuncture in improving migraine headaches in female patients.

Chronic migraine is associated with significant disability, psychological distress and decreased quality of life; its considered the second most common cause of devastating headaches.² In the U.S migraine accounts for 6-9% of men and 18-24% of women while 1.4% to 2.2% of general population suffer from chronic migraine.^{4,5} This translates to more than 27million women being affected by migraine in the U.S alone.⁵ The prevalence of migraine headaches have placed a great barrier on the U.S health care system by putting people out of work. It is estimated more than \$13billion and 113million work days are lost each year due to migraine headaches.⁴ In addition, over 3 million ER visits and 81,000 hospital admissions were made due to headaches. One third of the emergency visits and two third of the hospital stays were from migraine headaches.⁶

According to international classification of headache disorders (ICHD-II), chronic migraine is defined by a headache that occurs daily or for more than 15 days per month over 3 months. These headaches can be associated with aura or without aura, of all the attacks 8 of the episodes must meet migraine without aura or respond to traditional medications used for migraine.⁴ Because of this reason patients are forced to use medication around the clock for symptom relief. Medication over use has been associated with the formation of chronic migraine and failure of preventative methods.³ The treatment for chronic migraine does not revolve around cure, its focused on symptomatic therapy and prophylaxis. This usually includes NSAIDS, local injection of botulinum, topiramate, triptans, valproic acid, tanacetum parthenium, ergotamines and more. Some of the medication can be used to relieve the symptoms and also as preventative.⁴ These medications also carry numerous side effects that are intolerable for patients and cause further damage. In certain parts of the world alternative non pharmacologic therapies are being utilized to treat chronic migraine.⁷

The treatments mentioned above have shown to be mildly effective in treating migraine; however pharmacologic therapy increases the incidence of chronic migraine and is associated with increased side effects. The use of acupuncture has shown to be effective in treating migraine with minimal side effects. Acupuncture is also financially feasible compared to other pharmacologic treatments.⁸

OBJECTIVE

The objective of this selective EBM review is to determine whether or not acupuncture is effective in treating chronic migraine in women between the ages of 18-65.

METHOD

This systematic review includes two randomized control trials and one prospective control trial that focused on women between the ages of 18-65 years old with chronic migraine. These trials used acupuncture as the intervention comparing it to other treatment options. In the study by Facco et al comparisons were made by treating patients with valproic acid 600mg and traditional acupuncture.⁹ In the study by Ferro et al, patients were treated with tenacetum parthenium as well as a combination of acupuncture with tanacetum.⁸ The study conducted by Yang et al compared acupuncture therapy to topiramate.¹⁰ The outcomes measured included safety and efficacy, Improvement in quality of life and reduction in number of headache days.

All the articles were published in the English language. The author used pub med, EBSCOhost to search the articles using key words “acupuncture” and “chronic migraine”. All of the articles were published in peer reviewed journals. The author used clinical relevance and patient oriented outcomes as the main criteria to select the studies. The inclusion criteria included studies that were randomized control trials or controlled trials after 2009 that compared acupuncture to other conventional treatment options for chronic migraine. The main exclusion criteria included patient that were under 18 and above 65 years old. Summary of statistics reported or used includes p-value, NNT, ARR, RRR, SF-36, MIDAS, NNH. These results were calculated using the data in the study. Table 1 displays demographics and characteristics included in the studies.

Table 1 - Demographics & Characteristics of included studies

Study	Type	# Pts	Age (yrs)	Inclusion criteria	Exclusion criteria	W/d	Interventions
Facco (2013) ⁹	Controlled study	82	32-44	– Migraine without aura lasting for over one year – Frequency of	– Acupuncture treatment less than one year before – Prophylaxis with other migraine prophylactic	18	– Acupuncture performed according to traditional chinese

				migraine attacks equal to 3-8 per month	agents in the past 6 months – Secondary headache – Relevant coexisting organic or psychiatric diseases – Use of drugs potentially affecting migraine (e.g., beta blockers for cardiovascular diseases).		medicine for 30min with 25 or 40mm needle. - Valproic acid ER 600g daily
Ferro (2012) ⁸	RCT	69	18-56	– Age 18- 56 with diagnosis of migraine without Aura – Migraine attacks for at least 1 year – Average of 2-6 migraine attacks per month – Patients ability to distinguish between migraine and other headaches	– Hypersensitivity to study medications – Pregnancy – Intake of analgesics – Experience with more than 3 different migraine prophylactic drugs in the past – Drug misuse or dependency – Lack of compliance Psychiatric disorders, confirmed diagnosis of GI or CV complaints	1	Fixed and classic Acupuncture treatment of 20 sessions for 30min with 0.25 mm x 40mm needle. Administered over 10 weeks, 2 sessions per week. – 150mg powdered T parthenium Q HS
Yang CP (2011) ⁴	RCT	66	18-65	– Age 18- 65 – Established migraine history for at least 1 year	– Headaches other than chronic migraine – Migraine prophylaxis agents used in the past 3 months – Migraine onset after age of 50 or over 60 yo at onset of chronic migraine – History of severe illness – Cognitive impairment interfering with ability to follow instruction and describe symptom – Pregnancy or nursing – Severe depression	4	– Fixed and classic acupuncture treatment of 24 sessions for 30 min with 0.25mm x 40 mm needle. Administered over 12 weeks, 2 sessions per week. – 25mg Q HS of topiramate for 1 wk increased up to 100 mg in divided doses.

OUTCOME MEASURES

Each of the studies addressed a specific outcome that is relevant to the patient. The study by Yang et al looked at reduction in number of moderate/severe headaches, reduction in number

of days with migraine, improvement in quality of life and pain reduction. These were measured using 50% responders analysis, self reporting by participants and short form 36 (SF-36) and MIDAS.⁴ The study by Ferro et al looked at improvement of quality of life and impact of treatment in reducing pain by using visual analogue scale (VAS), migraine disability assessment (MIDAS) and short-form 36 (SF-36).⁸ The study by Facco et al looked at quality of life, level of patients suffering, impact of treatment in reducing pain, severity and frequency of attacks. Facco et al measured the outcome with MIDAS index (MI), pain relief score and headache diary recorded by patients.⁹

RESULT

This systematic review looks at two RCTs and one prospective controlled trial that address the efficacy of acupuncture in treating chronic migraine. This is accomplished by using the dichotomous data provided in the studies and calculating RRR, ARR, NNT, and NNH. These studies looked at reduction in intensity and frequency of migraine headaches as well as reduction in headache days and improvement in quality of life.

The study by Facco et al, included 100 patients that were diagnosed with migraine without aura. This patients were divided in to two groups, acupuncture (n=50) and valproic acid (n=50) treatment groups. The acupuncture group received 20 sessions per week of treatment in a specific acupoint locations which were selected based on Chinese traditional medicine, while the other group received valproic acid 600mg/day. The clinicians and study workers were not kept blinded to the treatment. The study lasted for 24 weeks; 18 out of 100 participants dropped out due to various reasons, 4 patients refused to take valproic acid, 3 patients were scared of needles, 9 patients had problem with work, 1 patient was lost to motor accident and 1 patient had a

tumor.⁹ At the conclusion 18% were lost to follow up. Intention to treat analysis was not used.

Facco et al used Midas questionnaire before treatment which showed no significant statistical difference; the questionnaire was repeated after 12 and 24 weeks of treatment which showed significant improvement in patient daily activity and number of headache days. The study reported total MIDAS score of 24 in both groups at the beginning of the study, as well as a midas score of 7 and 5 at 24 weeks in valproic acid and acupuncture groups respectively. Number of headache days was reduced from 17 to 6 and 18 to 4 for valproic acid and acupuncture groups respectively. These results have a statistical significance ($p < 0.0001$) in patients that achieved pain reduction and daily activity improvement (Table 2). Numbers needed to treat and harm were not calculated because the study did not provide number of patients that achieved reduction in headache days and improved daily activity.

Table 2: Number of headache days and MIDAS score after 24 weeks of treatment

Study	Number of Headache days at 24 weeks		MIDAS score at 24 weeks	
	Acupuncture	Valproic acid	Acupuncture	Valproic acid
Facco et al	4	6	5	7

In the study by Ferro et al a total of 69 women were divided in three groups. In this review we will focus on acupuncture (AC) and tanacetum (Tan) groups. AC (n=22) received 20 sessions of acupuncture in over 10 weeks, and Tan (n=23) received 150mg/day of tanacetum. One patient dropped out from AC group because of work related issues which translated to 1.4% of patients being lost to follow-up. Intention to treat analysis was not utilized in the study.⁸

After the treatment the patients social functioning (SF-36) were measured primarily using questionnaires. The same doctor was used to administer the questionnaires and was blinded to

the study in order to avoid bias. The study reported AC (SF=15.2) and Tan (SF=11.2); this shows a significant improvement in AC group compared to Tan group. The result showed statistically significant difference (p=0.008) in the patients that had improved quality of life. The dichotomous data represents RRR=36%, ARR=400% and NNT=1 (Table 3).

Table 3: social functioning and number needed to treat data

Study	Acupuncture SF-36	Tan (SF-36)	ARR*	RRR*	NNT*
Ferro et al	15.2	11.2	400%	36%	1

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

The study by Yang et al looked at patients that had significant reduction of moderate/severe headache days after the acupuncture and topiramate treatments. The study had 66 subjects that were randomly divided to acupuncture (n=33) and topiramate (n=33). The acupuncture group received 24 sessions in 12 weeks and topiramate group received 25mg/day titrated to 100mg/day by week 4 and maintained for 8 weeks. Over all 3 and 1 patients dropped out from topiramate and acupuncture groups owing to work related issues and significant side effects respectively. There were 6% of subjects that were lost to follow-up. Intention to treat was utilized in this study.

After the intervention patients response to treatment were assessed with 50% responder analysis which looked at moderate/severe headache reduction. A 50% reduction of headaches from base line were reported by 75.8% and 30.3% of acupuncture and topiramate group respectively.⁴ The results were statistically significant with p<0.1 between acupuncture and topiramate treated groups. This shows RRR=150%, ARR=45% and NNT=3, which means 3 patients needed to be treated with acupuncture to prevent 1 more person from having chronic migraine than control group (Table 4).

Table 4: 50% responder’s analysis to decreased number of headache days and NNT

	50% responders analysis Acupuncture	50% responders analysis Topiramate	RRR*	ARR*	NNT*
Yang et al	75.8%	30.3%	150%	45%	3

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

In the study by Facco et al adverse events were significantly higher in valproic acid group; 48.8% of patients reported nausea, constipation, abdominal pain, drowsiness, weight gain and itching. There were no patients that reported side effect from acupuncture therapy.⁹ The number needed to harm in this study was -2, which means for every 2 participants who used acupuncture there was one fewer incidence of adverse effect than the group taking valproic acid. The study by Yang et al reported 66% of patients to have intolerable side effects due to topiramate treatment. This side effect included paresthesias, memory disturbance, dyspepsia, fatigue, dizziness, somnolence and nausea. There were tolerable paresthesias and ecchymosis in 6% of the acupuncture group. The NNH was -1, meaning for every 1 patient with migraine using acupuncture, one fewer would experience adverse effects compared to control group. The study by Ferro et al reported minor similar side effects in acupuncture group as mentioned above. However it did not report the number of patients affected (Table 5).

Table 5: percent of patients with side effect

Study	Acupuncture	Control group	NNH
Facco et al	0	48.8%	-2
Yang et al	6%	66%	-1

DISCUSSION

The studies presented in this systematic review all support that acupuncture can be used to effectively treat patients with chronic migraine. The studies further support the use of acupuncture has limited side effect profile compared to using traditional medication used in the study. The statistical significance reported in all three studies was $P < 0.05$ which supports acupuncture is effective in treating chronic migraine. One study showed that the combination treatment of tanacetum with acupuncture is more effective than acupuncture alone.⁸ The other two studies showed acupuncture to be superior than control group.

The review has multiple limitations that are worth mentioning. The studies were not able to rule out placebo effect which could have possibly added to the group difference seen in the study. In addition, the studies had small number of patients which makes it difficult to apply the result to the general population with chronic migraine. These kinds of studies should be performed in a larger group of patients in order to have applicable data. Another limitation is the review only looked at adult patients between the ages of 18-65; however it's known that chronic migraine headaches can occur in the two spectrum of ages, the children and older adults.

All the studies used in this systematic review were not double blinded; the clinicians knew the subject and the treatment they were receiving. However the clinician performing the questionnaire was blinded and didn't know the groups, so the studies were single blinded. The follow-up period in these studies were not very long which added to the limitation. There was also limitation that occurred from searching for applicable randomized controlled trials, most studies looked at acute migraine treatment and prophylaxis and not chronic migraine.

In the United States and Europe acupuncture trained providers are increasing in number. After receiving the 4 year masters degree from an accredited oriental medicine (ACAOM), they

are allowed to conduct a comprehensive history and physical as well as perform the acupuncture technique to alleviate multiple symptoms.¹¹ This technique is being utilized greatly to treat common condition like back pain, osteoarthritis, nausea, vomiting, chronic pain syndromes and more.² It's reported that more than 18,000 licensed acupuncture providers and more than 3,500 licensed acupuncturist physicians are located in the U.S alone.¹¹ According to U.S health news, most insurance companies are not ready to cover for acupuncture unless the patient has a diagnosis and fail other regiments. Most patients are more likely to pay the cost out of packet per session.¹²

The use of acupuncture clinically has been published in different studies since 1970. In general very low and mild adverse effects are reported, including pain at the site, nausea vomiting and dizziness. The reported side effects are usually as low as 1 in 100,000.¹¹ Most major side effects occur due to inadequate training or lack of safe practice, such as broken needles, injury to organs and infections which are very rare. Acupuncture is contraindicated in patients with pregnancy, malignant tumors, bleeding disorders and in cases of emergencies.¹³ If performed in this conditions it can be detrimental.

CONCLUSION

In conclusion, the three studies included in this systematic review showed that acupuncture is an effective method in treating patients with chronic migraine. The results provide statistical significance that patients could benefit equal if not more relief from their chronic migraine by using acupuncture. The review also showed that there are minimal side effects from using acupuncture compared to traditional pharmacologic medications. More research on this topic can be useful to find out if long lasting relief can be acquired from using

acupuncture. It would also be beneficial to conduct further research on long term effect of acupuncture on the sensory pathways of the acupoints used. Currently an RCT is being conducted to see the long term effectiveness and prophylaxis benefit of acupuncture for migraine headaches.

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