Combining Acupuncture with Pharmacotherapy in Refractory Migraine: A Pilot Study

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Abstract

Complicated the medical problem is, harder it becomes to treat and the more treatment strategies exist. This observation stands true in the context of migraine treatment. Several large randomized trials, research reports have been published regarding effectiveness of acupuncture in management of headache, especially in migraine headaches. Cochrane review first considered the role of acupuncture in headache in 2001, but it showed many technical, methodological flaws in the majority of studies. Since then, several other trials in different nations have been done and published. However most of them have considered managing with acupuncture alone and they do not report of the patients having used medication, or using medication during acupuncture therapy which indicate of biasness. We tried to do a pilot study of starting acupuncture therapy to people who had migraine and poorly if not at all controlled with medications. We initiated a multi-central trial and tried to see the efficacy of the acupuncture therapy when combined with the medication to the people with the migraine poorly controlled with the medication alone. The participants were chosen on the basis of definition of refractory migraine and other inclusion criteria. They were evaluated pre and post acupuncture session. With the preliminary results coming positive and promising, we are hopeful of conducting a clinical trial involving comparison between pharmacotherapy and acupuncture with pharmacotherapy in migraine will bring a positive result.

Keywords
Refractory; Migraine; Sleep Disorder; Acupuncture; Pharmacotherapy; Pilot Study

Background
Migraine is a common disabling primary headache. According to the Global Burden of Disease Survey 2010, it was ranked as the third most prevalent disorder [1]. Epidemiological studies indicate that as high as 15% of female, and around 6% of male population experience headache related with migraine [2, 3]. While the GEM study, comprising two multi centers found about 33% of female population had migraine prevalence, substantial percentage of male were also suffering from migraine [4]. Quality of life in migraine sufferers is also severely affected in migraine people and their families [5]. Majority of migraine population is undertreated and continues to have bad quality of life. This segment of migraine population can benefit from the preventive therapy [6]. There have been several medicines tried for

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Received August 16, 2017; Accepted November 05, 2017; Published November 15, 2017

Citation: Avinash Chandra (2017) Combining Acupuncture with Pharmacotherapy in Refractory Migraine: A Pilot Study. SF J Surgery 1:2.

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preventive therapy for migraine [7]. Some of the medicines have shown a good control over headache and carry level a evidence in preventive therapy and abortive therapy [8, 9]. However, evidence-based review of the therapeutics of acute migraine is compromised by the quality of the evidence available and uncertain pathophysiology of migraine. Pharmacotherapy with beta blockers, calcium antagonists or other agents seem to be promising in reducing the frequency of migraine attacks but tolerability is suboptimal [10]. Pharmacotherapy for migraines also comes with the adverse effects like, dizziness, altered liver functions among others [11]. Despite of all these potential adverse risks, some are put on multiple medication for migraine prevention but fail to prevent. These are categorized as the refractory migraine [12, 13]. Acupuncture therapy has not such obvious adverse effects. Role of acupuncture for migraine preventive therapy however is obscured due to lack of a good level of evidence from research trial [14]. However it is one of the widely used therapy in migraine headache prevention [7, 15]. Combining acupuncture with the pharmacotherapy will reduce the load of medications to the migraine people and thereby reducing the chances of the adverse effects.

**Material and Method**

We chose to see the effectiveness of acupuncture when combined with the pharmacotherapy to the people with migraine who were refractory migraine. Refractory migraine emphasizes the lack of response to the pharmacotherapy [12]. To find the effectiveness of acupuncture on people with migraine, we set some inclusion and exclusion criteria (given as below) and grouped them accordingly. All the participants gave us the full consent for research purpose.

**Inclusion Criteria were:**
1. Patient 18 years or older
2. Chronic Migraine
3. Already on medications and not well controlled
4. No psychiatric issues

**Exclusion Criteria were:**
1. Patient 18 years or younger
2. Newly diagnosed migraine

3. Not under any kind of medication
4. Taking medication only occasionally and well controlled
5. Psychiatric issues
6. Withdrawal or no consent to the participation

We designed a self administered questionnaire. Each of the participants was given the sheet of questionnaires before and after finishing each session of acupuncture. The questionnaire consisted of several different elements (given somewhere). Each session consisted of acupuncture of around 2 weeks (16 days). After each session each participant were given the questionnaire. Their response were noted and collected and later analyzed. Only verum acupuncture was done. The acupoints chosen for migraine were : taiyang, hegu, shenmen, taichong, taixi, sanyinjiao, shuaigu and yintang.

**Results**

Among our participants, most of them (more than 50%) had headache of more than 6 days per week. 14% of them, had headache attacks more than 4 days but severe in nature. Similarly, as high as 28% of them had sleep disturbances. Nausea and vomiting was found in more than 70% of our participants and similar percentage. 70% had fatigue associated with migraine in our participants.

After the first session of acupuncture, participants showed significant changes in their existing problems. The frequency of headache decreased significantly in almost all of the participants among which 30% had no headache at all and were free of medications. 30% no change in frequency of headache but the intensity of it showed marked improvement. They had to take only one analgesics and it worked for the rest of the whole day. Majority of our participants had the complaint of nausea and vomiting associated with migraine. Nausea and vomiting showed a significant change. 50% of our participants got rid of these symptoms post acupuncture. Sleeping pattern also showed better post acupuncture session. Sleep was seen frequently disturbed in our migraine participants. The sleep disorder was assessed through the sleeping questionnaires. Fatigue symptom however did not show any significant changes post acupuncture session. Some of the participants also showed betterment in mood. Before acupuncture session they had bad mood usually aggravated with headache.
which got better along with the headache after acupuncture session.

**Discussion**

Headache remains the most common cause of consultation in clinical practice and thus a proper diagnosis and better treatment is imperative [12, 16, 17]. Refractory migraine was defined as the migraine (according to International Classification of Headache Disorder) that is not controlled with adequate trials of multiple preventive and or abortive medicines alone or in combination [12, 18]. The refractory migraine not only affects the daily life activities but it also affects the family. Therefore there have been many different therapeutic trials conducted on migraine for better control of migraine. Traditional Chinese Medicine theory states that acupuncture is capable of inducing its long lasting effect and thus provides better result. Several trials of acupuncture in migraine have been conducted [15, 19]. The results have been mixed with majority showing the better control over migraine. However several studies are biased, or have other technical flaws [19]. The unclear mechanism of acupuncture has only fueled to the controversy of its role in headache management. There are some researches done which indicate the possible mechanism on the cellular and functional level in central nervous system as evidenced by the fMRI finding [20]. The functional and interdependence is shown better with fMRI [21]. Acupuncture (especially the verum acupuncture) can increase the connectivity of the default mode network [21] with the pain and the sensorimotor network with pain related regions [22]. In a study by Qin et al., with fMRI study found that acupuncture may change amygdala-specific brain network into a functional state that modifies pain perception and pain modulation [20].

In our study we used acupuncture therapy as a complimentary to the ongoing pharmacotherapy. Acupuncture was chosen with the idea that acupuncture modulates the pain circuit and its effect is long lasting [20]. In accordance with this, our participants showed a marked improvement in headache severity and marked improvement in headache frequency as well. There is a positive relation between migraine and poor sleep quality [23, 24]. Our participants suffering from migraine with sleep disordered showed significant improvement in sleeping pattern post acupuncture session. The improvement in disturbed sleep has been found in many papers and systemic reviews [25, 26]. The accurate mechanism of acupuncture on the sleep centre isn’t fully understood though.

**Limitation of Study**

There were few limitations of this study, mainly being the small sample size. However, we have planned to carry out the study with large sample size. Although we tried to minimize the bias of the study, still we assume the study to be biased as there was no way to blind the participant about acupuncture. Another major limitation of this study is the obscure pathophysiology of acupuncture.

**Conclusion**

This was a single centered pilot study where we carried out the study with small sample size. The result has come out significantly positive. There was not only improvement of migraine headache frequency but even the intensity of headache seemed improving. The sleeping pattern was also improved impressively. The combined effect of acupuncture and preventive medication to patients with the refractory migraine would be very helpful. The medication over usage and its potential side effects can be minimized by utilizing acupuncture therapy.

**References**


