

Acupuncture For Migraine Prophylaxis: A Randomized Control Trial by Li et al

Name

Institution

www.nursingtermpapers.com

Recurrent and chronic headaches are a major source of morbidity and costs are substantial (Li *et al.*, 2012). Understandably, medical researchers are looking for more cost effective treatments for this condition. Acupuncture is widely used for the treatment of headaches in industrialized countries and it may be applied as a single modality as well as part of a more complex treatment program. Despite this popularity, there is still debate about whether acupuncture has ‘specific’ effects, that is, effects over and above placebo. (Li *et al.*, 2012).

In this research, the authors conducted a single blinded, randomized controlled trial for a period of 21 months in nine big hospitals in the Republic of China. Patients were invited mainly through the media and hospital clinics. They administered 20 sessions of electro-acupuncture to the patients through either sham acupuncture points or one of the three traditionally based Chinese medicine acupuncture point’s prescriptions for more than five weeks. The interest of the author was to obtain some data on the specificity of acupuncture for migraine prophylaxis, with the outcome of the clinical procedures measured in ‘the number of days with headaches’ as listed in a headache diary (Li *et al.*, 2012). Migraine Specific Quality of Life questionnaire was used to determine the secondary outcomes at baseline 4, 8 and 16 weeks (Li *et al.*, 2012).

Four hundred and eighty patients were placed into the four trial groups thus giving allowance for those who will drop out and a 95% strength of statistical significance of a decrease in the number of headaches of 1.5 days migraines each month. Majority of the trials fulfilled that acupuncture offers benefits in the treatment of headache. However, the assessment of physical forms of treatment that includes acupuncture poses certain difficulties and thus specialized

parameters in the study design need to be considered. Acupuncture techniques require individualization, a carefully chosen placebo, and the crossover design should have enough time between the two treatment periods. Clinical trials that evaluate acupuncture are often characterized by numerous inadequacies. However, an extra clinical research is usually needed to confirm its effectiveness and elucidate its indications (Li *et al.*, 2012).

No significant differences in the number of days with migraine were noticed between the three TCM groups after 8 weeks upon review of the headache diary. However, at the 16th week, some placid clinical changes were noticed. As determined by the MSQOL questionnaire, Sham Acupuncture was less effective than Acupuncture (Li *et al.*, 2012).

Screening procedure of the trial was comprehensive in ensuring a homogeneous set and eased the bias of using a volunteer set for conducting trials. The screening procedure involved considering the International Headache Classifications procedure for migraines with and without Aura, aged between 19 and 65 and with the appearance of migraines before the age of 55 years. The volunteers experienced chronic migraines two times a month for more than a year for the four months preceding the trial (Li *et al.*, 2012). For the month preceding the trial, the volunteers had to take a headache diary and abstain from taking prophylactic migraine medicine. Patients who had headaches of organic nature were excluded for the study. It looks to be the trend to pre-publish trial protocol and designs before a study is started and Li *et al.*, (2012) quoted themselves in both the intervention and randomization part of their article. This has a scale of “hassling factor” for the reader, as an additional search would be needed for another article.

Acupuncture is a therapeutic method developed in the structure of traditional Chinese medicine and has been used for more than 2,500 years. In the past, acupuncture analgesia has generated the interest of practitioners in several medical fields. The National Institute of Health Consensus Conference on Acupuncture has evaluated the usage of acupuncture in relieving several syndromes. Pertaining the efficacy of acupuncture for headache, it concluded that acupuncture could only be used in a comprehensive treatment program. This is in contrary with the Li, *et al.*, (2012) research conclusions that advocates for the administration of acupuncture as an adjunct treatment (Li *et al.*, 2012).

The biggest question with Li, *et al.*, (2012) study is whether the 1.5 headache days is significant for people averaging 5.6 to 6.4 days of migraines every month. Even taking the best case, reducing an individual from 5.6 to 4 days every month gives us an improvement of only 30%. Even placebo has 35% probability of triumphing. On the PEDro scale, 8 of 12 criterions were satisfied in the trial. However, this case did not guarantee that there was data to proof that the treatment discussed was clinically of any use (Li, *et al.*, 2012).

The use of Sham Acupuncture as a control experiment in the trial is my key issue. Sham Acupuncture is not a noble intervention. Upon piercing the skin, the mediator nerves of healing, the immune, and the humoral systems respond, and the DNIC pain roots are reactivated. Further, it is proved that a positive expectation of a treatment can positively influence a patient's neuron-matter and consequently his/her overall reaction. The conclusion given by the authors is confusing; that acupuncture's influence for the migraine prophylaxis is negligible and is grounded on the treatment groups' effect at 16 weeks not comparing to Sham Acupuncture the way the research design expects the reader to infer (Witt, *et al.*, 2006). This compromises the

clarity of the trial. I would be tempted to presume the author is not in a fix trying to decide whether to give the true or sham acupuncture at practice. Use of 'no treatment control' would have been more effective, perchance to show that acupuncture has more than 'negligible' effect on migraine prophylaxis in comparison with a no treatment situation (Witt, *et al.*, 2006).

When randomizing and getting informed consent, patients were told that they would be given acupuncture on basis of either the 'modern acupuncture theory' or one of the three TCM methods. I infer that calling sham acupuncture 'modern acupuncture theory' is trying to stretch the truth. The authors argue that electro-acupuncture is common in China and its usage on sham acupuncture points was to 'lighten the chances of unblinding'. There were no references cited to prop up the use auxiliary needles as an electrotherapy technique. The previous reading of Han's work would suggest use of spinal segmental pairing of electrodes (Witt, *et al.*, 2006). Using a non-validated technique reduces the reader's capacity to draw a conclusion from the trial (Witt, *et al.*, 2006).

During this research, prerequisite studies were performed in the Western countries (Li, *et al.*, 2012). However, acupuncture is a highly rated form of treatment in China since it is a part of its tradition. During this study, this general acceptance could influence the patient's opinion concerning the efficacy of acupuncture by influencing the effects of placebo (Witt, *et al.*, 2006). Twenty treatments of electro-acupuncture over 4 weeks would even challenge the staunchest of willing acupuncture patients. The current private consultation fees would cost \$1000. Observing only 'clinically minor' effects means it would be a 'tough sell' if the practitioners can only extrapolate possible improvements to the patients in a duration of 4 to 8 weeks of window post treatment. It is disappointing that comparisons are done to only two other studies in the whole

discussion. The authors' conclusion is also very simplistic. Their study does not prove that 'acupuncture seemed to have clinically minor effects for migraine'. It proved that a sole and a yet to be validated electro-acupuncture method emerged to have a clinically negligible effect for migraine at eight weeks post simulation. However, the authors acknowledge the shortcomings of their research, particularly the petite follow up period, self-reporting, the non-blinding of practitioners conducting the acupuncture and the generalization of the western population (Witt et al., 2006).

According to the data available from this research, using acupuncture to treat headache seems promising because the majority of the clinical trials elicited positive conclusions concerning its efficacy. However, an evaluation of the physical forms of treatment administration, which includes acupuncture, presents unique difficulties, and thus particular parameters in the study design need consideration. Acupuncture techniques need to be individualized, the type of placebo chosen with care and the crossover design must allocate enough time between the two treatment periods. The minimum acupuncture seems to be the best method (Witt et al., 2006). While, overall, acupuncture seems to be beneficial, it is unclear which treatment strategies – points, type of stimulation or frequency – applied by which provider groups are the most promising for a defined group of patients. While acupuncture is not free of risks, it seems to be relatively safe in the hands of qualified providers. Therefore, headache patients who want to try acupuncture should not be discouraged. Existing provision of acupuncture to headache patients also seems justified. The question of which particular type of acupuncture should be offered, cannot be answered at present (Witt et al., 2006).

Li, *et al.*, (2012) commendably tried an extensive set of trials to seek the top electro-acupuncture point selection for migraine prophylaxis but unsuccessful to provide clinical importance for the acupuncture physician in my opinion. This is disappointing with Li *et al.*, (2012) experience in related studies in the management of chronic migraine attacks. Thus, the results of this trial should be considered cautiously and may not be applicable to New Zealand practitioners (Witt *et al.*, 2006).

References

- Li, Y, Zheng, H., Witt, C.M., Roll, S., Yu, S., Sun, J....Liang, F. (2012). Acupuncture for migraine prophylaxis: A randomized controlled trial. *Canadian Medical Association Journal*, 184(4), 401-410. Retrieved from:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291669/>
- Witt .C. M, (2010). Efficacy, Effectiveness, Safety and Costs of Acupuncture for Chronic Pain - Results of a Large Research Initiative. *Japanese Acupuncture and Moxibustion*, 24 (2): 16-21. Retrieved from: <http://www.jsam.jp/onlineJournal/fullpaper.php?id=47>
- Yu .S., *et al.*, (2007). Randomized Controlled Trial to Treat Migraine with Acupuncture: Protocol and Design – *Trials*, 8 (56). Retrieved from:
<http://www.trialsjournal.com/content/9/1/57>