



Editorial on “The long-term effect of acupuncture for migraine prophylaxis: a randomized clinical trial”

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Comment on: Zhao L, Chen J, Li Y, *et al.* The Long-term Effect of Acupuncture for Migraine Prophylaxis: A Randomized Clinical Trial. *JAMA Intern Med* 2017;177:508-15.

Abstract: Migraine is a common and disabling headache disorder. This Editorial examines the role of acupuncture for migraine prophylaxis. In particular, the results from a recently published randomized sham-controlled trial on acupuncture for migraine prophylaxis in migraine without aura are discussed in the context of previous literature. Acupuncture appears to be a safe and efficacious treatment for migraine prophylaxis, although the optimal frequency of treatment is unclear.

Keywords: Acupuncture; complementary medicine; migraine

Received: 15 March 2017; Accepted: 26 March 2017.

doi: 10.21037/amj.2017.04.05

View this article at: <http://dx.doi.org/10.21037/amj.2017.04.05>

Migraine is a common, disabling and recurrent headache disorder (1). Due to the limitations of existing prophylactic medications, migraine sufferers frequently turn to complementary therapies to alleviate their headaches (2). Acupuncture is one of the most popular complementary therapies used to treat migraines. This Editorial examines the recent publication of a randomized sham-controlled trial on acupuncture for migraine prophylaxis (3).

Acupuncture is a Chinese medical therapy which involves insertion of fine metal needles into prespecified points on the body (4). Being a complex physical intervention, it is challenging to conduct high-quality clinical research on acupuncture. Some of the methodological challenges include controlling for the strong non-specific effects of acupuncture (which include the placebo response), and the difficulty of creating a control method which mimics acupuncture but maintains physiological inertness (5,6).

A Cochrane review (7) on acupuncture for migraine prophylaxis, updated in 2016, reported that acupuncture exerts a small but significant effect over sham acupuncture, and a larger effect when compared with usual care or no treatment. A reduction of 2.5 migraine attacks per month (just under 50% improvement assuming a baseline

frequency of six attacks) could be expected with true acupuncture, whereas sham acupuncture could be expected to reduce migraine frequency by two attacks a month, and no treatment by one attack a month. The findings of this review were limited by the significant heterogeneity between trials, for example with regard to different “doses” of acupuncture that were delivered, and different types of sham controls that were used.

Zhao *et al.* (3) have since published results from their randomized sham-controlled trial on long-term effects of acupuncture for migraine prophylaxis in patients with migraine without aura. The trial compared three arms: true acupuncture, sham acupuncture, and waitlist control. Acupuncture and sham acupuncture were given 5 days a week for 4 weeks. Participants in the true acupuncture group experienced a mean 67% improvement in migraine frequency after 16 weeks post randomization, while the sham acupuncture group reported a mean 42% improvement. These effects were persistent at 24 weeks post randomization.

This was a well-conducted and large clinical trial originating from China, with several strengths. First, it is one of the larger trials on acupuncture for migraine prophylaxis,

with 249 participants randomized. The dropout rate was very low, with 245 participants included in the analysis. Randomization and allocation concealment were performed adequately, and outcome assessors were blinded. Validated outcome measures were used.

Of note, electro-acupuncture was delivered to both the true and sham acupuncture groups, with the only differences being the location of points, and obtaining “de qi” (De qi, or needle sensation, is considered an essential component of acupuncture treatment) (8). Electrical stimulation of acupuncture points may be more effective than manual stimulation. This point is important because the Cochrane review found only one trial delivered electro-acupuncture. The impressive results from Zhao *et al.*'s study suggest that electro-acupuncture may be superior to manual acupuncture for migraine prophylaxis.

There are several limitations to Zhao's study that need to be considered. One is the high frequency of treatment that was provided, which is consistent with usual practice in China but not in Western countries. It is unclear if daily acupuncture treatment is more effective than weekly or twice weekly, although sub-analysis from the Cochrane review (7) suggested that a larger effect was seen in trials that delivered 16 treatments compared with trials that delivered fewer treatments. As the cost of acupuncture is borne privately by consumers in most Western countries, it may be that attending for 20 treatments is prohibitive for some. The time commitment for this level of frequency may also be a deterrent. However, it must be noted that after the initial month of treatment, there was a sustained improvement for almost 6 months. This equates to 15 days without migraine over 6 months that would otherwise be spent experiencing a migraine, if acupuncture had not been delivered. Moreover, use of rescue medication (ibuprofen) fell dramatically in the acupuncture group compared to the waitlist control group. The time and financial cost of attending for an initial course of acupuncture may be mitigated somewhat by the savings in work productivity and medication costs. Recent health economic analysis in the USA (9) indicates that the annual direct and indirect costs of episodic migraine equate to \$1,705 and \$943 respectively. 70% of the direct cost, or \$1,196, relate to the use of pharmaceuticals. However, future research should explore the optimal frequency of treatment for this condition.

Another limitation is that the outcome measure for migraine frequency is subjective. This is of course not limited to migraine, but extends across many of the painful conditions, and to other conditions such as mental health.

There are no biomarkers for migraine (10), neither did this present study explore the potential biological mechanisms by which acupuncture exerts its effects. These mechanisms remain unclear, although a recent animal study suggested a serotonergic mechanism (11).

This new, rigorous, sham-controlled study confirms the efficacy of acupuncture over sham acupuncture for migraine prophylaxis, which was concluded from a recent Cochrane review. Practice points for clinicians can be summarized as follows:

- (I) The evidence strongly suggests that acupuncture is efficacious for migraine prophylaxis;
- (II) Electro-acupuncture (electrical stimulation of acupuncture points) may be more effective than manual stimulation;
- (III) The optimal frequency of acupuncture treatment is unclear, however it appears that an initial course of acupuncture can have sustained results over 6 months;
- (IV) The analgesic effects of acupuncture cannot be fully explained by non-specific (including placebo) effects, as acupuncture has demonstrated superiority over sham acupuncture;
- (V) The present study was specific to migraine without aura only;
- (VI) Acupuncture appeared to be safe, with adverse events being infrequent and minor in this study;
- (VII) Acupuncture should always be delivered by trained professionals.

Acknowledgements

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned and reviewed by the Section Editor Zongshi Qin (Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing, China).

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/amj.2017.04.05>). Dr. Ee reports that he is a practicing acupuncturist.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/amj.2017.04.05

Cite this article as: Ee C. Editorial on “The long-term effect of acupuncture for migraine prophylaxis: a randomized clinical trial”. *AME Med J* 2017;2:54.