

Acupuncture studies: are they done with sham or scam?

Abstract

There is a rising body of studies that erroneously concludes Acupuncture to be “ineffective” based on studies done with “sham Acupuncture” used as a negative control. These same studies and others show that both sham and traditional Acupuncture have significant benefit compared to non-Acupuncture treatment. However, the differences in outcome between “sham” and traditional Acupuncture technique are small when compared to each other, but still more effective than non-Acupuncture treatment. Sham Acupuncture methodology is not standardized in any way and can be similar to acupressure or alternative Acupuncture techniques. Given the benefits of any Acupuncture technique, including so-called “sham” techniques, compared to non-Acupuncture, the data suggests that the sham Acupuncture methodology is not acting as a reliable negative control.

Keywords: sham acupuncture, childbirth, hypertension, labor induction, eclampsia, placebo, clinical controlled study

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Introduction: sham acupuncture methods and controlled studies

In practice, “sham” Acupuncture comes in several varieties. One type inserts needles into non-traditional sites but otherwise mimics traditional Acupuncture. For this form of “sham” Acupuncture to serve as a control, the subject must be ignorant of where the needles are traditionally stuck or blinded to where the needles are being stuck perhaps by a screen and an anesthetic. Another type of sham Acupuncture uses a method that prevents the needles from actually being inserted into the body, whether at traditional or non-traditional points. If the false Acupuncture takes place at traditional acupoint, there is no need to prevent the patient from seeing where the fakery is taking place. This method requires the subject to feel like he’s been stuck even if he hasn’t. It is important that the patients in the sham group think they are getting true Acupuncture. Ideally, the patients in the true Acupuncture group wouldn’t know whether they were getting true or sham Acupuncture. It is equally important that the acupuncturist not indicate to the subjects in any way whether she is delivering true or sham Acupuncture. Any acupuncturist delivering sham Acupuncture has to be an actor and be careful not to provide the subjects with any information. Any study where the subjects can easily detect whether they are getting true Acupuncture is a compromised study because it cannot measure the placebo effect unless, of course, one assumes that the only thing one is measuring when measuring the effectiveness of Acupuncture are placebo effects.

Sham Acupuncture comes in different varieties and there is no real consensus of how to perform it.¹ When reading this description of sham methods the reader could come to the conclusion that the task of providing a negative control in this treatment procedure is nearly impossible to achieve. The author suggests that the above described procedures of “sham Acupuncture” in fact resemble the techniques used in acupressure² and many Japanese styles of Acupuncture.³ It has long been known that acupressure and Japanese Acupuncture techniques are very effective and that is precisely the reason why there is very little statistical difference between real and sham Acupuncture outcome in these studies.

Example 1: Acupuncture and high blood pressure

There are few studies published that simply compare Acupuncture vs. no-Acupuncture control groups. This study on Eclampsia⁴ shows a significant effect on lowering blood pressure compared to the control group. As a matter of fact the control group had no change in blood pressure or showed a slight increase. Arguably, this example is a very small study but there are many large studies available on Chinese Herbal treatments studies on Eclampsia in China. This is because patients in China most always receive both Acupuncture and Herbal Medicine.⁵ From these studies there is no doubt that Acupuncture and Herbal Medicine is effective in reducing blood pressure. Acupuncture and Chinese Herbs are standard treatment regimens for hypertension in China and Taiwan and other parts of Asia.

This “real vs. sham” Acupuncture study however concludes that Acupuncture does not work for reducing blood pressure.⁶ How is it possible? It was reasoned that there is no difference between real and sham groups. The article states: “We found no evidence of an improvement with the fact that Acupuncture relative to sham Acupuncture in SBP change (n = 386; mean difference = -3.80mmHg, 95% CI = -10.03-2.44mmHg; I (2) = 99%)” It was concluded that Acupuncture does not have an effect of lower blood pressure despite of the findings that both study groups had a significant statistically lowered blood pressure. In the eyes of this author these conclusions do not make sense.

Example2: Acupuncture and childbirth

How effective is Acupuncture for the management of pregnancy and childbirth. A study that clearly shows the effectiveness of Chinese Medicine in childbirth.⁷ It was concluded that Acupuncture treatment is an important and effective tool in their ability to reduce the extent of intervention throughout the birth process and also in reducing child delivery completion interventions.

This article on childbirth and Acupuncture using the real vs. sham Acupuncture controlled studies⁸ once again concluded that there is no statistically significant effect: “Eighty women were randomized and 75 women completed the study procedure. Age, BMI, parity

and gestational age were similar in both groups. Spontaneous labor was initiated in 94.7 % of Acupuncture group and 89.2 % of sham Acupuncture group ($p = 0.430$). There were no statistically significant difference between groups for time from enrollment to delivery ($p = 0.06$).

Conclusion

According to this study, it seems that Acupuncture was not effective in labor initiation compared to sham Acupuncture.”

Ajori et al.,⁸ shows infact that Acupuncture was 94.7% effective for labor induction. Sham Acupuncture is nearly as effective (89.5%). Is Sham Acupuncture a valid negative control? In the light of a 94% positive result, is it really logical to conclude that Acupuncture is not effective just because there is no significant difference to sham control?

According to Declercq et al.,⁹ more than four out of ten respondents (41%) indicated that their care provider tried to induce their labor, with three out of four of those women (74%) indicating that it did start labor resulting in an overall rate of medically induced labor of 30%. The truth is that 40% of all pregnancies are chemically induced with only 74% effectiveness leading to at least 26% of birth needing C-sections. According to the Center of Disease Control, C-section are performed at an even higher rate of up to 35% overall.¹⁰

The author argues again that with an effectiveness of over 90% these studies do show in fact⁸ that Chinese Medicine is outstanding in the management of pregnancy and childbirth, significantly reduces the time of labor and has the potential of reducing the rate of C-sections to a rate below 10%.

Discussion

In order to study the effectiveness of Acetaminophen for the treatment of headaches, one can find a clear example of a double blind study that is easy to plan, execute and understand here.¹¹ This study clearly shows that acetaminophen works 20% better than placebo (the placebo was 32% effective). However 48% of subjects receiving “real” acetaminophen still had headaches after 2hours. And once again attempts are made to study Acupuncture effects on headaches in a real vs. sham fashion¹² state no statistical difference between the 2 groups. The Author believes that this type of study on headaches as described for acetaminophen is simply not possible for Acupuncture. Sham Acupuncture is not comparable to a “sugar pill” in lieu of the “real” drug. Sham Acupuncture is infact actually a form of real Acupuncture. The author concludes that all these so called “controlled studies” show that Sham Acupuncture is probably a form of acupressure treatment with very similar but consistently lower effectiveness as when using needles (as already explained above). As a matter of fact patients stabbed with blunted needles can’t really tell the difference,¹³ Tough et al.,¹⁴ further enforces the idea that sham techniques are very effective. However interestingly in all these studies there is a measurable difference to “real” Acupuncture. This aspect however remains a topic for another article.

In support of the claims of this article, Hopton and McPherson¹⁵ actually sums up very nicely: “we ask the question: is it now time to shift research priorities away from asking placebo-related questions and shift toward asking more practical questions about whether the overall benefit is clinically meaningful and cost-effective?”

Conclusion

The author suggests looking at the real results of these studies and discarding the procedure of “sham” Acupuncture. Sham controlled Acupuncture studies are poorly done and the conclusions drawn from “Sham” Acupuncture are irrelevant and convolute the scientific and public opinion on the real effectiveness of Acupuncture. The discussion on the topics of Acupuncture and Hypertension and Childbirth as discussed in this article is good examples on this topic. Just to be perfectly clear, the issue here is not whether different studies support different outcomes or results. Instead the Author is pointing out the fundamental flaws of the conclusions drawn from clinical studies performed with sham vs. real Acupuncture. The effectiveness of Chinese Medicine can simply no longer be ignored and downplayed in these so called “controlled” studies.

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Conflicts of interest

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