Written by Christina Stephens Monday, 06 July 2009 00:00

When one sees press release headlines like, "For Women with Polycystic Ovarian Syndrome, Acupuncture and Exercise May Bring Relief, Reduce Risks", as seen here, one tends to assume that the content of said press release concerns a specific alternative medicine procedure in which fine needles are inserted into specific parts of the body for therapeutic purposes based on the hypothesis that the needles can alter "energy". When one reads the text of the press release, one is greeted with, "Exercise and electro-acupuncture treatments can reduce sympathetic nerve activity in women with polycystic ovarian syndrome (PCOS), according to a new study."

Electro-acupuncture and acupuncture are two different things and should not be used synonymously. There are countless studies documenting the effects of applying electric currents to bodily tissues without inserting needles into the skin in the process. Because the headline and body of this article virtually uses "electro-acupuncture" synonymously with "acupuncture", people may read the headline of the study or the article itself [1] and come to the conclusion that acupuncture may be effective. In the press release, they interchange the words "electro-acupuncture" with "acupuncture" freely, using the word "electro-acupuncture" and "acupuncture" 8 times each.

If electrical therapy (given via a TENS unit or other non-invasive modality) is equally as effective as electro-acupuncture therapy, then electro-acupuncture therapy is unethical, as it puts a participant at unnecessary risk of complications. I did an Article First, Pubmed and Academic Search Primer search for studies comparing electro-acupuncture therapy to some type of non-invasive electrical therapy. I found no comparisons. Such comparisons need to be made in order to establish whether or not inserting needles is more effective than a noninvasive technique. Occam's Razor applies here. If 1 + 1 = 2, and 1 + 1 + X = 2, where X has potential side effects (such as punctured lungs, paraplegia, subarachnoid hemorrhage, infection, endocarditis, and so on), then applying X to participants is unethical and unnecessary.

Aside from the obvious misuse of "electro-acupuncture" and "acupuncture" as synonyms, there are serious weaknesses with the actual article.

1.

The treatment, comparison and control groups were a. an electro-acupuncture treatment group in which electro-acupuncture was administered by one of the authors of the study, b. An exercise group which was given instructions on performing specific exercises and thereafter called once per week for additional guidance and c. a group of women who could

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call the study coordinator at any point. All three groups were given information packets on the importance of exercise and healthy diet. The experimenters were not blinded to which group women were in, and clearly the women were not blinded to which treatment group they were participating. This nonblinding is a serious problem for the article, as is the fact that the treatment group received much more personal interaction with the researchers than the other two groups.

2.

Many measurements were taken: Height, body weight, BMI, sagittal abdominal diameter, waist-to-hip ratio, hyperandrogenism, insulin levels, muscle sympathetic nerve activity (MSA), and women documented their menstrual bleeding pattern. Of all of these measurements, only changes in MSA, sagittal abdominal diameter and BMI correlated with the groups. Both the exercise and the electro-acupunture (EA) group had decreased MSA compared to the control group. The EA group was correlated with reduced sagittal diameter, and the exercise group was correlated with reduced BMI compared to the control group. There were no differences between the other variables. When one takes many different measurements, the likelihood of one of those measurements being a statistically significant anomaly increases.

3.

Effect size: though statistically significant (I.E. a result unlikely due to pure chance) correlations were reported, the authors did not report effect size. A lot of published research (especially alternative medicine research) will report "significant" differences, but will not state whether or not these differences are large enough to warrant the claim that we have detected a phenomena. According to Overall [2], "A rare statistical association may have no effect on the biology of the system, but could misdirect incautious readers to believe that this was not the case". Thus, to really say something meaningful about the differences in treatment groups, one has to say something about effect size. It is always possible to show that there is significant difference between two groups, unless they are 100% Identical. The important part is to what *degree* groups are different. For this, you need to know the effect size. Incidentally, effect size takes little time to calculate, so I question why it was excluded. I calculated effect size for the significantly different variables in the study and found the effect size to be miniscule. For example, EA baseline sagittal diameter was 20.1±4.7cm and after 16 weeks was 19.3±4.6cm, for an average reduction in sagittal diameter (measured by laying participants flat on a table and measuring the distance between the exam table and the highest position of the abdomen, which sounds like a very inexact way to measure sagittal diameter) of .9cm. The effect size was .08. A "small" effect size is described as being between 0.1 and 0.3[3].

4.

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Small sample size: Though 504 women were recruited, 404 did not meet the inclusion criteria. The remaining 100 were examined, and 84 women were determined to be eligible. 10 more participants dropped out before baseline measurements. Only 23 participants were measured at the outcome, and of those 23, only 20 were "successfully" measured. Why the researchers only measured 23 out of 74 women *is not explained*. So, we're left with 20 participants.

In addition to the limitations above, one possible mechanism for the change in sympathetic nerve activity measurements is that it is a product of circumstance and environment. Participants are typically instructed to relax during acupuncture treatments. Over the course of many treatments in which a participant is instructed to relax in a particular environment and by particular practitioners, the participant may associate relaxation with these environmental factors. If the participant's sympathetic activity were measured in the same lab and by the same researchers who administered the treatment, then the subjects trained to relax in such an environment may relax more than individuals who were not. Relaxation and meditation are associated with changes in sympathetic nerve activity [4]. Thus, what researchers may have been measuring is a difference in stress response to the environment between groups.

Thus, not only are electro-acupuncture and acupuncture not synonymous, this article does little to convince me that electro-acupuncture is effective at "bringing relief" for women affected by PCOS. If we are to establish the validity of electro-acupuncture or any other alternative medicine, we must hold the methodology of research to the same standards as science-based medicine. This can be done by conducting double blind, placebo controlled trials in which individuals with a vested interest in the outcome do not take part in the trials, especially as it occurred in this study.

References:

- 1. Stender-Victorin E, Jedel E, Janson PO, Sverrisdottir YB. Low-frequency Electro-Acupuncture and Physical Exercise Dosage Decrease High Muscle Sympathetic Nerve Activity in Polycycstic Ovary Syndrome. Am J Physiol Regul Integr Comp Physiol 2009; (In press)
- 2. Overall, K., Dunham, A., Homeopathy and the curse of the scientific method. *The Veterinary Journal* (2009)



180: 141-148

- 3. Cohen J (1988). Statistical Power Analysis for the Behavioral Sciences (second ed.). Lawrence Erlbaum Associates.
- 4. Lang R, Dehof K, Meurer KA, Kaufmann W Sympathetic activity and transcendental meditation. Journal of Neural Transmission 2005;44:117-135

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