

Academic Debate

Discussion on the curative effect of acupuncture for polycystic ovarian syndrome

关于针刺治疗多囊卵巢综合征疗效的讨论

HAO Yang (郝洋), LIU Wei-hong (刘炜宏)✉

Institute of Acupuncture-Moxibustion, China Academy of Chinese Medical Sciences, Beijing 100700, China

ARTICLE INFO

First author: HAO Yang (1987-), female, assistant editor.

Research field: Research on modern literature of acupuncture-moxibustion.
E-mail: wjam1991@sina.com

✉ Corresponding author: LIU Wei-hong (1957-), female, senior editor.

Research field: Study of acupuncture-moxibustion theory and standardization.
E-mail: weihongliu010@sina.com

Accepted on 1, September, 2017.

ABSTRACT

Discussion on the negative result of the paper “Effect of acupuncture and clomiphene in Chinese women with polycystic ovary syndrome: a randomized clinical trial” from Chinese experts were organized, and experts from Beijing, Nanjing, Chengdu who’s major were clinical acupuncture, acupuncture research and gynecology have made their points. In-depth discussion were made by the experts from the perspective of confirmation of therapeutic program, selection of outcome indices, application of statistical analysis, the illustration of research results and clinical effects. The experts have pointed out that the negative result is commonly seen in medical research and the key point is to find out the defects of the trial so as to modify the research orientation and better serve the clinical practice.

KEY WORDS: polycystic ovarian syndrome; acupuncture; live birth rate; randomized controlled trial

BACKGROUND

A team with professor WU Xiao-ke, the director of obstetrics and gynecology department of The First Affiliated Hospital, Heilongjiang University of Chinese Medicine and Dr. Elisabet Stener-Victorin, a Swedish expert in reproductive endocrine and metabolism as the co-first authors published a randomized clinical trial report which was entitled as “The curative effect of acupuncture combined with clomiphene citrate for treatment of polycystic ovarian syndrome in Chinese women” on *The Journal of the American Medical Association (JAMA)* online (Wu X K, Stener-Victorin E, Kuang H Y, Ma HL, Gao JS. *JAMA* 2017; 317 (24): 2502). The study aimed at verifying whether the single use of acupuncture or acupuncture combined with clomiphene citrate (CC) can increase the live birth rate of women with polycystic ovarian syndrome (PCOS). The subjects recruitment started from July 2012, and the last live baby was born in

October 2015, with the recruitment lasting for more than 3 years. The research team consisted of several experts in gynecology, reproductive medicine and biomedical statistics from Chinese Mainland, Hong Kong-China, Sweden and the United States, and totally 27 cooperative units in China participated in this study. The study was a large-scale clinical trial carried out on the basis of professor WU Xiao-ke’s related researches in the recent ten years. However, the results of study were very different from the previous papers published by professor WU Xiao-ke, and also different from the experience and viewpoints of clinicians in China and other countries. As a result, furious repercussions have been aroused in the international acupuncture field. As a medical clinical trial, the negative results was normal. The key points were how the negative results were obtained, and how to treat these negative results. It was a little overgeneralized to completely negate the therapeutic effects of acupuncture for some diseases only by virtue of one or two research reports. Some

viewpoints of Chinese experts about this study are as follows.

Whether the two therapeutic regimens were formed according to clinical practice, and whether there was study which can certify that the therapeutic regimen was a mature scheme

LIU Bao-yan (Principal Researcher of China Academy of Chinese Medical Sciences): Did the therapeutic regimen generated from long-term clinical practice or was merely the author's assumption? Has preliminary trial been conducted with regard to the curative effect of this regimen? According to our clinical experience, local acupoint selection was emphasized for gynecological diseases, especially the ovarian diseases, including Zīgōng (子宫 EX-CA 1) and *Luàncháo*. In this regimen, these acupoints were not used, and only some acupoints in the head and limbs were selected. Therefore, the unsatisfactory efficacy was predictable.

The primary outcome for polycystic ovarian syndrome should be the recovery of ovulation function

WANG Shu-yu (Chief physician and professor of Beijing Obstetrics and Gynecology Hospital): the outcome of this study was that the fetus can live healthily for 20 weeks after birth. However, the curative effect for treatment of polycystic ovarian syndrome should be determined based on whether there is ovulation or not. There are too many factors affecting the live birth rate, including sperm quality, endometrium, uterus, general physical condition, and abortion, etc. Clinically, pregnancy cannot be ensured on the basis of ovulation, and the fetus may not be born on the basis of pregnancy. Treatment was conducted for 16 weeks (2 times a week) in this study, but the conditions after at least six months since the completion of the treatment were observed. How were the interference factors controlled during this period? In particular, it was a multi-center study, and the influencing factors of each center were certainly different. So the live birth rate was a little far away as an outcome. If we only observed whether CC plus acupuncture was effective or not, the ovulation rate can be compared, and a control group can be set up in order to exclude the case of natural ovulation function recovery.

Before the study of the combination of acupuncture and drug, the curative effect of single use of drug or acupuncture should be first determined in order to determine

whether the combined use can increase the curative effect

ZHU Bing (Former Director of Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences): Whether has the author conducted the effect study of single use of acupuncture or clomiphene citrate for treatment of polycystic ovarian syndrome? Or whether has the author understood their effects? On this basis, it was necessary to design a study on whether the combined use of the two methods can improve the curative effect instead of determining whether one of the two methods was effective. Since diseases are complex, and the human bodies are also complex, in some cases, the combined use of multiple therapies may not achieve the effect of $1+1>2$.

There is basically no negative results published in China. The publication of the paper may help to strengthen the concept of scientific clinical research in acupuncture-moxibustion discipline

XU Bin (Chairman of Clinical Branch of CAAM): the paper has reminded us that we must pay attention to the negative results in the process of scientific research since there is basically no negative results in China. The results of professor WU Xiao-ke's team can provide a better idea for future studies.

The live birth rate of acupuncture combined with clomiphene citrate has reached 29.4%, which has been higher than that of the single use of CC in the clinical trials of western medicine led by professor Richard S. Legro in 2014 (19.1%), why was it said to be ineffective?

LIU Wei-hong (Deputy Secretary-general of China Association of Acupuncture-moxibustion, executive deputy editor of *WJAM*): in the results of the study, the live birth rate in acupuncture plus CC group was 29.4%, and the live birth rate in sham acupuncture plus CC group, as a control, was 28.0%. The conclusion of ineffectiveness was generated from this comparison because that the differences were not statistically significant. There were two key questions: firstly, can the fact that the difference between the acupuncture plus CC group and the sham acupuncture plus CC group was not statistically significant indicate that the treatment method was ineffective? In fact, sham acupuncture plus CC was also effective. Secondly, since curative effect has been obtained in the sham acupuncture plus CC group, the results of the study was false negative. It can be seen from

Download English Version:

<https://daneshyari.com/en/article/8694280>

Download Persian Version:

<https://daneshyari.com/article/8694280>

[Daneshyari.com](https://daneshyari.com)