

# Acupuncture and PCOS: A Pilot Study

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**Abstract:** *Background:* Polycystic Ovarian syndrome (PCOS) affects approximately 6-10% of women of reproductive age. Symptoms can include menstrual abnormalities, anovulatory infertility, hirsutism and insulin resistance. Women with PCOS also have an increased risk of cardiovascular disease and diabetes. Past studies have demonstrated that acupuncture is a potential treatment method for PCOS that has very few side effects. However, there have been very few studies evaluating the efficacy of acupuncture in PCOS patients. The aim of this pilot study is to evaluate the effect of acupuncture in PCOS patients. *Methods:* This study involved the consideration of real body acupuncture group in the management of menstruation for women with PCOS. Each subject received real acupuncture treatment once a week for a period of twelve weeks. The study occurred over seven months which consisted of one month run in period, three months intervention period and three months follow up period after the completion of intervention. *Results:* A total of 11 PCOS patients were recruited for the pilot study with 7 included for statistical analysis. There was a statistical difference between the pre-test and post test scores of Progesterone and Menstrual Pattern in women who received acupuncture treatment. *Conclusion:* This pilot study suggested that acupuncture may have a role in menstruation regulation and impact on the ovulation mechanism and/or ovarian luteal functions. Properly performed acupuncture together with other measures might provide a new approach for fertility regulation.

**Keywords:** PCOS, Acupuncture, Infertility.

## INTRODUCTION

Polycystic Ovarian syndrome (PCOS) affects approximately 6-10% of women of reproductive age [1]. Symptoms can include menstrual abnormalities, anovulatory infertility, hirsutism, elevated androgens, elevated oestrogen levels, insulin resistance and obesity [1]. Women with PCOS also have an increased risk of cardiovascular disease and diabetes due to  $\beta$  cell dysfunction and insulin resistance [2]. Current conventional treatment methods include use of pharmaceutical agents such as gonadotropins, clomiphene citrate, gonadotropin-releasing hormone analogs and surgical methods including assisted reproduction techniques and laparoscopic ovarian drilling. However an optimal treatment method has not yet been identified [3].

Past studies have found that repeated electro-acupuncture treatments can induce regular ovulation in women with PCOS through modulation of the neuroendocrine system [4]. Animal models have also shown that acupuncture can potentially reduce insulin resistance [5]. Thus acupuncture is a potential treatment method for PCOS that has very few side effects. However, there has been very few studies

evaluating the efficacy of acupuncture in PCOS patients. The aim of this pilot study is to evaluate the effect of acupuncture in PCOS patients. This study was performed in the Liverpool Hospital of Sydney Australia in 2006-2007. Ethics approval was obtained from the Human Ethics' committee of the Liverpool Hospital, Sydney South West Area Health Service, Department of Health, NSW, Australia.

## METHOD

### Inclusion Criteria

Subjects who were over 18 years old and met the following PCOS diagnostic criteria set by the 2003 Rotterdam consensus were included in the study [6].

Any patient with presence of 2 out of 3 criteria as listed below was considered as having PCOS:

- oligo/anovulation
- hyperandrogenaemia
- polycystic ovaries

Subjects were recruited from those seeking acupuncture treatments for symptoms of PCOS through the Chinese Medicine Clinical Research Centre of the Liverpool Hospital Sydney. The PCOS diagnosis was made by an independent gynaecologist

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who is not part of the research team in this project. Screening tests at entry included a full blood count, renal and liver function tests, blood hormone level tests including a pregnancy test, and transvaginal ultrasound. Ultrasounds were performed by the Radiology Department of Liverpool Hospital Sydney or Rayscan Radiology Centre at Liverpool, Sydney.

### Procedure

This study involved the consideration of real body acupuncture group in the management of menstruation for women with PCOS. Each subject received real acupuncture treatment once a week for a period of twelve weeks by an Australian acupuncturist who was registered with the Chinese Medicine Registration Board of Victoria (the only State in Australia where has statutory registration in place for acupuncturist at time of this project being carried out). The pilot study occurred over seven months which consisted of one month run in period, three months intervention period and three months follow up period after the completion of intervention.

All subjects received the following body acupuncture points throughout the pilot study regardless of their individual Chinese Medicine Syndrome differentiation of PCOS:

- Guanyuan - Ren 4
- Zhong Ji - Ren 3
- Zi Gong - Ex-CA-18 (Bilaterally)
- Sanyinjiao - SP6 (Bilaterally)

### Outcome Measures

The primary outcome measure was the return of menstruation from amenorrhea over a 3 month period while the secondary outcome measures were the

changes in LH/FSH concentration and LH:FSH Ratio and in androgenic hormone concentration.

The clinical parameters were measured through Self-assessment scores (including Visual Analogue Scale) every fortnight for physical symptom improvement, menstrual loss and timing as well as through the weight or body mass index of the patient. Symptomatic parameters include the menstrual loss at the conclusion of the post-intervention follow-up. Transvaginal ultrasound of ovaries was performed by an expert ultrasonographer at the Early Follicular Phase in the patient's menstrual cycle, and the number and size of ovarian cysts recorded. Endocrine measures on the other hand were conducted at pre and post treatment during the early follicular phase. This included Serum Testosterone, Sex hormone-binding globulin (SHBG), Free Androgen Index (FAI), Luteinising Hormone (LH), Estradiol, Progesterone, Follicular Stimulating Hormone (FSH), and LH:FSH Ratio. Hormonal tests of Androstenedione, Dehydroepiandrosterone Sulphate (DHEAS), and 17-Hydroxyprogesterone were performed prior to the commencement of intervention. All endocrinological testing were performed at the early follicular phase of the subject's menstrual cycle (if there is any).

### Statistical Analysis

For the statistical analyses, because this pilot study concerned with the improvements of the clinical and laboratory measurements, data analysis focused on comparing mean scores. Paired samples *t* tests was conducted to compare the clinical and laboratory measurements of participants in the pre and post-tests.

## RESULTS

A total of 11 PCOS patients were recruited for the pilot study. Out of the 11 patients, 9 patients had

**Table 1: Pre Test Results**

| Subject | Pre LH | Pre FSH | Pre LH:FSH | Pre Progesterone | Pre FAI | Pre Testosterone | Pre Menstrual Pattern (Days) |
|---------|--------|---------|------------|------------------|---------|------------------|------------------------------|
| 1       | 5.5    | 6       | 0.916      | 2                | 9.4     | 1.7              | 180                          |
| 2       | 12     | 4       | 3          | 4                | 18      | 3.8              | 80                           |
| 3       | 19     | 4       | 4.75       | 5                | 22      | 2                | 120                          |
| 4       | 9.5    | 6       | 1.583      | 3                | 15      | 1.8              | 150                          |
| 5       | 11     | 3       | 3.667      | 3                | 10      | 3.1              | 90                           |
| 6       | 11     | 4       | 2.75       | 2                | 8.5     | 2.8              | 180                          |
| 7       | 7.6    | 7       | 1.085      | 2                | 9       | 2.2              | 50                           |

**Table 2: Post Test Results**

| Subject | Post LH | Post FSH | Post LH:FSH | Post Progesterone | Post FAI | Post Testosterone | Post Menstrual Pattern (Days) |
|---------|---------|----------|-------------|-------------------|----------|-------------------|-------------------------------|
| 1       | 1.3     | 4        | 0.325       | 1                 | 6.4      | 1.4               | 35                            |
| 2       | 9.6     | 4        | 2.4         | 1                 | 15       | 33                | 35                            |
| 3       | 8.9     | 4        | 2.225       | 2                 | 14       | 3.3               | 30                            |
| 4       | 7.6     | 6        | 1.266       | 2                 | 7.8      | 1.8               | 30                            |
| 5       | 9.8     | 2        | 4.9         | 1                 | 7.4      | 2.6               | 90                            |
| 6       | 9.5     | 6        | 1.58        | 2                 | 6.3      | 1.3               | 40                            |
| 7       | 5       | 7        | 0.714       | 3                 | 7        | 1.8               | 28                            |

**Table 3: Paired Samples t-Test Results**

|                   |       |    |                 |                 |                       | 95% Confidence Interval of the Difference |         |
|-------------------|-------|----|-----------------|-----------------|-----------------------|-------------------------------------------|---------|
|                   | t     | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | Lower                                     | Upper   |
| LH                | 1.702 | 12 | 0.115           | 3.414           | 2.006                 | -0.957                                    | 7.785   |
| FSH               | .168  | 12 | 0.869           | 0.143           | 0.849                 | -1.707                                    | 1.993   |
| LH:FSH            | .791  | 12 | 0.444           | 0.620           | 0.784                 | -1.088                                    | 2.329   |
| Progesterone      | 2.465 | 12 | 0.030           | 1.286           | 0.522                 | 0.149                                     | 2.422   |
| FAI               | 1.636 | 12 | 0.128           | 4.000           | 2.445                 | -1.327                                    | 9.327   |
| Testosterone      | -.894 | 12 | 0.389           | -3.971          | 4.441                 | -13.649                                   | 5.706   |
| Menstrual Pattern | 3.839 | 12 | 0.002           | 80.286          | 20.914                | 34.718                                    | 125.853 |

clinical presentations of amenorrhoea while 2 had irregular menstruation prior to acupuncture intervention. Out of the 11 patients recruited for the pilot study, 1 patient was excluded as the diagnostic criteria of PCOS were not met and 3 dropped out half way through the study. Therefore 7 patients were included in the study for analysis. Tables 1 and 2 present the pre-test and post-test results of the PCOS patients respectively.

The results of the paired samples *t*-test are shown in Table 3. The difference between the pre-test and post test scores of Progesterone ( $t = 2.465$ ,  $p = 0.030$ ) and Menstrual Pattern attained a significant difference ( $t = 3.839$ ,  $p = 0.002$ ).

As indicated from Table 4, most of the measures parameters had decreased after the acupuncture intervention and only Testosterone had been reported to increase after administering acupuncture to the participants.

## DISCUSSION

According to Chinese Medicine (CM), many diseases are caused due to the loss of balance

**Table 4: Direction of Change**

|                   | Mean Score |       | Direction of Change |
|-------------------|------------|-------|---------------------|
|                   | Pre        | Post  |                     |
| LH                | 10.80      | 7.39  | Decrease            |
| FSH               | 4.86       | 4.71  | Decrease            |
| LH:FSH            | 2.54       | 1.92  | Decrease            |
| Progesterone      | 3.00       | 1.71  | Decrease            |
| FAI               | 13.13      | 9.13  | Decrease            |
| Testosterone      | 2.49       | 6.46  | Increase            |
| Menstrual Pattern | 121.43     | 41.14 | Decrease            |

between Yin and Yang [7]. More specifically it is observed that diseases can be caused by weakened or excessive organ functions [8]. As per the Polycystic Ovary Syndrome (PCOS), the key pathogenesis is because of the deficiencies in kidney and/or liver functions. Due to the combination of these two factors, the kidney and/or the liver fail to disperse the qi and the blood, which manifests in the form of key signs and symptoms of PCOS. Hence the CM treatment should concentrate on restoring the deficiencies at the same time promoting the qi and the blood flow within the reproductive organs.

For the purpose of the study, key acupoints were selected to promote the qi and the blood flow within the reproductive organs and to restore the kidney deficiency (Guanyan (Ren 4), Zhong Ji (Ren 3), Zi Gong (Ex-CA-18) and Sanyinjiao (SP 6)).

The results obtained from the pilot study supported some of the previous case reports at the and also found some additional data which was not found in the previous studies. One of the earlier studies by Takeshi *et al.* [9] found that there was a significant variation in the plasma levels of four hormones in the pre-ovulatory phase under acupuncture stimulation. According to Takeshi *et al.* [9] the plasma levels of LH, FSH and estradiol fluctuated at different time durations under acupuncture stimulation. However, in our pilot study, all hormonal parameters showed a decreased level except testosterone. Mo *et al.* [10] conducted a study that employed a non-randomised clinical trial with a small control group on 34 patients to evaluate the effectiveness of acupuncture on ovulation stimulation. The authors concluded that "acupuncture has some good regulatory effect on the endocrine indices of the HPO axis, including a bi-directional regulatory effect on FSH, LH and oestradiol." Our pilot study supports this finding.

Another study by Stener-Victorin *et al.* [4] was a non-randomised, longitudinal study consisting of 24 patients between the ages 24 and 40. The purpose of the study was to evaluate the effectiveness of electro-acupuncture on oligo-ovulation and/or anovulation and other related endocrine features in PCOS. The study suggested that acupuncture could be used to stimulate and regulate menstrual pattern and ovulation with repeated sessions. This finding was found to be consistent with the result of the current pilot study. However, it was found that the mean inter-menstrual days among the subjects decreased from 121 days to 41 days with respect to the current study.

It is interesting to note that the mean testosterone level appeared to be increased at the post treatment period in this pilot study. It is important to note that one of the subjects (subject no. 2) had a marked testosterone level (from 3.8 to 33) before and after the increase acupuncture intervention, leading to the elevated mean testosterone level despite most of the other subjects have recorded lower testosterone level post intervention. Nevertheless, single measurements may not be accurate as fluctuations are known to vary the result, in particular the difficulty to define early follicular phase for blood collection in this pilot study.

Progesterone level showed a downward trend pre and post acupuncture intervention. Despite the downward trend showed by a p value < 0.05, these differences may still be arisen due to chance due to its small sample size.

In this pilot study, all recruited subjects received the same acupuncture prescription regardless of their CM syndrome differentiation. This has in no doubt created non-reliable individual clinical outcomes. It must also be pointed out, however, that if the internal validity of the study was compromised due to bias and errors being introduced in one or more of the components of this pilot study, such as pre and post assessments, sample selection, randomization, credibility of acupuncture treatment, and/or the potential carry-over effects at crossover, they may affect the outcome in this study. Therefore, it may be possible to have committed a Type I error, leading to the incorrect rejection of one or more of the null hypotheses and therefore a false acceptance of one or more of the alternative hypotheses. Furthermore, it was also noted in this study that it is often difficult to define early follicular phase in women with irregular menstruation. This has made the blood collection, timing of the ultrasound become difficult for the study. Another limitation to this pilot study is the sample size. Given its small sample size, the probability for any clinical or hormonal changes noted in this pilot study by chance cannot be ruled out. From our understanding this was the first pilot acupuncture study being carried out in Australia during that period of time. Based on the results of this pilot study, our research team has then further carried out a randomised controlled study regarding to the use of acupuncture on PCOS, which will be published as a separate article.

## CONCLUSION

This pilot study suggested that acupuncture may have a role in menstruation regulation and impact on the ovulation mechanism and/or ovarian luteal functions. Properly performed acupuncture together with other measures might provide a new approach for fertility regulation.

## ACKNOWLEDGEMENT

This project formed part of the PhD (awarded) study of author DL who has received full postgraduate scholarship support from the South Western Sydney Clinical School, University of New South Wales, Sydney Australia.

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Received on 03-04-2014

Accepted on 05-04-2014

Published on 30-06-2014

DOI: <http://dx.doi.org/10.14205/2309-4400.2014.02.01.6>© 2014 Lim *et al.*; Licensee Pharma Publisher.

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