

The Effects of Laser Acupuncture Versus Ultraviolet Radiation on Ovarian Parameters in Obese Women with Polycystic Ovarian Syndrome: A Randomized Controlled Trial

Wafaa M Kamal, Ph.D.¹, Ahmed M Maged, M.D.², Asmaa M Elbandrawy, Ph.D.^{3,4},
Donia M Elmasry, Ph.D.⁵, Ebtesam A Ali, Ph.D.⁶, Dina M Aleshmawy, Ph.D.^{3,7}

¹Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Benha University, Benha 13514, Egypt.

²Department of Obstetrics and Gynecology, Kasr Al-Ainy Hospital, Cairo University, Cairo 11632, Egypt.

³Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Cairo University, Giza 12621, Egypt.

⁴Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Alsalam University, Gharbia 31512, Egypt.

⁵Department of Physical Therapy for Cardiovascular/Respiratory Disorder and Geriatrics, Faculty of Physical Therapy, Cairo University, Giza 12621, Egypt.

⁶Department of Physical Therapy for Basic Sciences, Faculty of Physical Therapy, Cairo University, Giza 12621, Egypt.

⁷Department of Physical Therapy for Women's Health, Faculty of Physical Therapy, Galala University, Suez 43511, Egypt.

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Abstract:

Objective: Complementary therapies are important in the treatment of polycystic ovarian syndrome (PCOS) **Aim:** This study was designed to assess the response of serum follicle-stimulating hormone (FSH), body mass index (BMI), serum 25-hydroxyvitamin D (25OHD), waist circumference (WC), serum luteinizing hormone (LH), LH/FSH ratio, and mean follicular size to laser acupuncture maneuverer (LAM) versus ultraviolet radiation (UVR) in PCOS women.

Material and Methods: One hundred five women were randomly divided into 3 equal groups: A, B, and C. The number of PCOS women within each group was 35. All groups received 500-mg metformin 3 times weekly. For group A, 2-minute LAM was applied to women's selected acupoints 3 times weekly. For group B, 3 UVR sessions weekly for 12 weeks were applied on PCOS women's abdomen for 10–20 minutes. Before and after 12 weeks, FSH, BMI, 25OHD, WC, LH, LH/FSH ratio, and mean follicular size were assessed.

Results: A significant improvement in PCOS women's outcomes was reported in the 3 groups. Besides the significant decrease in LH, BMI, LH/FSH ratio, and WC, the comparison of outcomes' post values among groups A and B or groups

Contact: Donia M Elmasry, Ph.D.

Department of Physical Therapy for Cardiovascular/Respiratory Disorder and Geriatrics,
Faculty of Physical Therapy, Cairo University, Giza 12621, Egypt.
E-mail: doniaelmasry2024@gmail.com

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A and C showed a significant increase in FSH, mean follicular size, and 25OHD toward group A. Also, the comparison of outcomes' post values among groups B and C documented a significant decrease in LH, BMI, LH/FSH ratio, and WC in addition to the significant increase in FSH, mean follicular size, and 25OHD toward group B.

Conclusion: Adding LAM or UVR to metformin can improve PCOS.

Keywords: acupuncture, laser acupuncture, metformin, polycystic ovarian syndrome, ultraviolet

Introduction

One of the main signs in women with polycystic ovary syndrome (PCOS) is the documented abnormalities of androgen hormones, such as the excessive production of luteinizing hormone (LH), relative insufficiency/decrease in the production of follicle-stimulating hormone (FSH), and unbalanced/irregular LH/FSH ratio¹.

It is documented that insulin resistance and/or hyperinsulinemia aggravate PCOS-related symptoms/signs via increasing the disturbances in the synthesis/production of ovarian androgens and elevating the production of free testosterone that contributes to PCOS-induced poor growth of follicles². Also, PCOS-associated insulin resistance is closely/highly linked to vitamin D deficiency, one of the highest reported problems in women with PCOS³.

The chronic/long-term use of metformin – used for the treatment of insulin resistance and symptoms of PCOS – may be limited by unpleasant gastrointestinal side effects (diarrhea and nausea) and metformin-induced lactic acidosis⁴.

One of the alternative therapies of PCOS is the non-invasive laser acupuncture maneuver (LAM) that is considered non-invasive, safe, easy to administer, requiring little/short time, and helping women⁵ who are afraid of invasive needling during traditional manual/electrical acupuncture⁶⁻⁹.

Conversely, ultraviolet therapy (UVT), a form of electromagnetic therapeutic radiation, is a well-known physiotherapeutic tool/device that is used in the treatment/management of muscular, periarticular, and rheumatic

pains/inflammations¹⁰. According to wavelength, UVR is classified into UVR-A type (the wavelength of this type ranges from 320–400 nm), UVR-B (the wavelength of this type ranges from 280–320 nm), and UVR-C (the wavelength of this type is <280 nm)¹¹.

Regular exposure to the main type of UVR, UVR-B, not only improves PCOS-related excess androgen hormones¹² but also decreases/prevents the occurrence of cardiovascular risk factors and metabolic complications¹³ and creates vitamin D from the skin's sterol precursors such as 7-dehydrocholesterol. The latter is transformed into the active metabolites/subcomponents of vitamin D in the subject's liver and kidney¹¹.

This study aimed to compare the effect of UVR-B versus LAM on ovarian parameters in obese women with PCOS.

Material and Methods

The Ethical and Medical Committee of The Faculty of Physical Therapy (Cairo University) approved the applied therapies (LAM and UVR) and PCOS-related assessments. The approval number is P.T.REC/012/004090. During the period of conducting LAM or UVR in women with PCOS, Helsinki recommendations were followed.

Based on the 2004 Rotterdam ESHRE/ASRM criteria¹⁴, 105 nulligravid women with PCOS were enrolled. The body mass index (BMI) of women with PCOS ranged from 30 to 40 kg/m². Also, the age of the included 105 women with PCOS ranged from 25–35 years old.

Exclusion criteria

Women with PCOS were excluded if they had one of the following problems: intake of ovulation induction medications, malignancies, hyperprolactinemia, intake of photosensitizing medications or contraceptive pills, hypothalamic and/or pituitary dysfunctions (documented via a low level of serum gonadotropin), dysfunctions of thyroid disease, congenital defects in the uterine cavity, Cushing's syndrome, or intake of hormonal medications or complementary therapies in the past 24 weeks. PCOS women with renal/hepatic disorders, alcoholism, or cardiac disorders were excluded.

Women with the following UVR contraindications were excluded: localized abdominal hypertrophic scarring or keloids, allergic reaction to UVR therapy, acute/chronic skin diseases, history of photosensitivity, autoimmune diseases (e.g. lupus), photochemical erythema, localized abdominal skin graft or damage, or photosensitizing medications.

Randomization

A computerized block list randomly assigned 105 women with PCOS into 3 equal groups: group A (LAM plus metformin), group B (UVR plus metformin), and group C (metformin only). The number of women with PCOS was 35 in every PCOS group (Figure 1).

Interventions

Metformin

For three months, all the women in the three groups with PCOS received metformin (500 mg Cidophage tablets, manufactured by The Egyptian Company for Chemical Industries Development (CID Pharma), Cairo, Egypt). Cidophage tablets were administered three times daily.

Laser acupuncture maneuver

According to previous studies^{5,15-18}, all of the following selected acupoints were stimulated in all the patients of the LAM plus metformin group: Conception

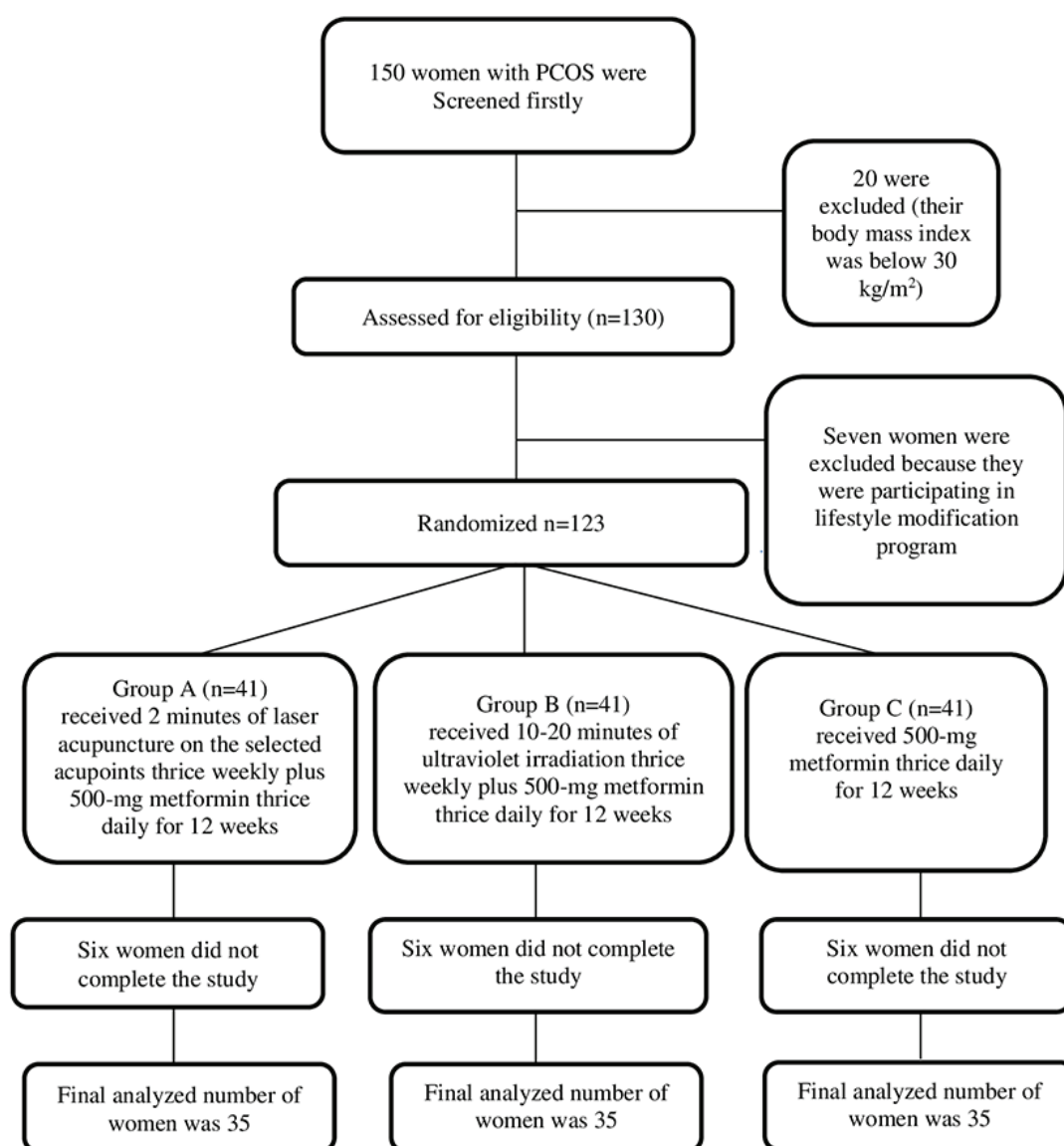
vessel acupoint 3 (CV3)^{16,17}, conception vessel acupoint 4 (CV4)^{15,18}, conception vessel acupoint 5 (CV5)⁵, conception vessel acupoint 6 (CV6)¹⁵⁻¹⁷, conception vessel acupoint 9 (CV9)¹⁸, conception vessel acupoint 10 (CV10)¹⁵, conception vessel acupoint 12 (CV12)^{15,18}, stomach acupuncture point 25 (ST25)^{15,17,18}, stomach acupuncture point 28 (ST28)¹⁵, stomach acupuncture point 29 (ST29)^{5,16,17}, stomach acupuncture point 36 (ST36)¹⁸, spleen acupuncture point 6 (SP6)^{5,16-18}, and spleen acupuncture point 9 (SP9)^{16,17}.

The skin of the above-mentioned acupoints was stimulated via direct perpendicular contact from the probe of a gallium arsenide infrared laser. The wavelength of this laser device was 904 nm and its power was 5mW. The applied energy density/output of the device was 2 J/cm². The output frequency of the device was 5000 Hertz and the time of pulse radiation was 200 ns. For 3 months, in the group of LAM plus metformin, LAM was applied to women's selected acupoints for 2 minutes 3 times weekly.

Ultraviolet radiation therapy

The protocol of Essa et al.¹⁹ was used in this study and the application was on women's exposed abdomen. Women with PCOS were placed in a sideways position, allowing their abdomen to face the UVR device/equipment (Quattro UVR-B device, 280-320 nm). To lessen or inhibit the reflection of UVR, alcohol was applied/spread on PCOS women's abdominal area. The applied power of UVR was 0.396 W/cm². At a 100-cm distance, the device was perpendicular to the abdomen of the woman. For 10-20 minutes, the session was applied. The first 10-minute session was initiated at 50% of the overall UVR dose, which was 470 mJ/cm². This was the customized/calculated suberythral dose of UVR that is suitable for different skin phototypes, mainly class III and IV.

From the second session, there was an incremental elevation of 10% of the total UVR dose (approximately 47 mJ/cm² for one minute per session as long as there were no adverse/side effects reported by the women with PCOS,



PCOS=polycystic ovarian syndrome

Figure 1 Flow chart of women with polycystic ovarian syndrome

such as persistent erythema, itching sensation, or skin burn. During the sessions, the therapist and women utilized/used safety glasses (goggles) to protect their eyes from UVR. All the women in the group of UVR plus metformin received 3 UVR sessions weekly for 12 weeks.

Outcomes

Besides BMI and waist circumference (WC), serum levels of PCOS women's LH, FSH, LH/FSH ratio (this ratio was the primary outcome of this study), and 25-hydroxyvitamin D (25OHD, the most accurate indicator

for in-serum levels of vitamin D) were assessed. Also, for monitoring/examining women's mean follicular size, vaginal ultrasound was executed.

Sample size calculation

LH/FSH ratio of women with PCOS was the primary outcome during the by-G*Power calculation of PCOS women's sample size. Ten pilot-test women with PCOS in every group were utilized for by-MANOVA sample-size calculation (the test selected at 90% power). The effect size of the LH/FSH ratio was 0.23 and the total number of women with PCOS required was 105 women (n=35 women in every PCOS group). To avoid a 17% drop/loss of women, 6 women with PCOS were added to each group.

Statistical analysis

PCOS women's basic data or outcomes were normally distributed (based on the results of the Shapiro test). Regarding PCOS women's basic data, one-way ANOVA was used to assess the between-group significant differences before starting interventions of LAM, UVR, or metformin. Regarding PCOS women's outcomes, MANOVA was used to assess the between-group and/or within-group significant differences either before starting or after ending interventions of LAM, UVR, or metformin. Significant

differences in PCOS women's basic data or outcomes were considered at p -value<0.05 using version 18 of SPSS.

Results

Before starting all therapies in the 3 groups, basic data (Table 1) and outcomes (FSH, BMI, LH, WC, 25OHD, LH/FSH ratio, and mean follicular size) showed a non-significant difference among the 3 treated PCOS groups (Table 2).

This study showed a significant improvement in PCOS women's outcome data (FSH, BMI, LH, WC, 25OHD, LH/FSH ratio, and mean follicular size) within the 3 groups after 12 weeks. Besides the significant decrease in LH, BMI, LH/FSH ratio, and WC, the comparison of outcomes' post values among groups A and B or groups A and C showed a significant increase in FSH, mean follicular size, and 25OHD toward group A (the group that received LAM plus metformin). Also, the comparison of outcomes' post values among groups B and C documented a significant decrease in LH, BMI, LH/FSH ratio, and WC in addition to the significant increase in FSH, mean follicular size, and 25OHD toward group B (the group that received UVR plus metformin) (Table 2).

According to MANOVA analysis, there was a statistically significant efficacy of applied treatments in

Table 1 Descriptive statistical parameters of PCOS women

PCOS women's parameters	Group A (LAM plus metformin)	Group B (UVR plus metformin)	Group C (metformin)	p-value
Age of women with PCOS (year)	29.42±2.78	29.28±3.01	30.11±2.82	0.440
Body mass index of women with PCOS (kg/m ²)	32.48±1.65	32.91±1.83	33.09±2.13	0.380
Waist circumference of women with PCOS	87.71±6.57	89.80±7.68	90.28±8.43	0.104
Annual number of menstrual cycles in women with PCOS	7.28±1.77	7.68±1.90	6.82±1.68	0.140
Duration between menstrual cycles in women with PCOS (day)	70.60±7.17	72.62±6.37	70.94±6.70	0.409
Duration of PCOS (month)	42.54±4.56	43.91±4.18	44.14±4.40	0.261

Expression of women's data was as mean±standard deviation, UVR=ultraviolet radiation, PCOS=polycystic ovarian syndrome P=probability (all values in this table are non-significant). LAM=laser acupuncture maneuver

Table 2 Women's outcomes in this PCOS trial

	Group A (LAM plus metformin)	Group B (UVR plus metformin)	Group C (metformin)	p-value between PCOS groups		
	mean±S.D.	mean±S.D.	mean±S.D.	A vs B	A vs C	B vs C
Body mass index of women (kg/m ²)						
Pre 12 weeks	32.48±1.65	32.91±1.83	33.09±2.13	1	0.533	1
Post 12 weeks	28.41±1.71	30.89±1.74	32.11±2.08	<0.001*	<0.001*	0.021*
Within-group p-value	<0.001*	<0.001*	<0.001*			
Waist circumference (cm)						
Pre 12 weeks	87.71±6.57	89.80±7.68	90.28±8.43	0.762	0.481	1
Post 12 weeks	76.65±6.96	82.31±9.18	88.34±10.35	0.028*	<0.001*	0.017*
Within-group p-value	< 0.001*	<0.001*	0.004*			
Luteinizing hormone (mIU/mL)						
Pre 12 weeks	10.62±1.35	10.65±1.63	10.42±1.56	1	1	1
Post 12 weeks	7.39±1.30	8.40±1.67	9.35±1.67	0.024*	<0.001*	0.036*
Within-group p-value	<0.001*	<0.001*	<0.001*			
Follicle-stimulating hormone (mIU/ mL)						
Pre 12 weeks	3.81±0.93	4.09±1	4.30±1.01	0.699	0.112	1
Post 12 weeks	6.59±1.29	5.68±1.08	4.56±1.04	0.004*	<0.001*	<0.001*
Within-group p-value	<0.001*	<0.001*	0.043*			
LH/FSH ratio						
Pre 12 weeks	2.55±0.55	2.62±0.52	2.81±0.69	1	0.227	0.559
Post 12 weeks	1.14±0.26	1.96±0.34	2.51±0.62	<0.001*	< 0.001*	<0.001*
Within-group p-value	<0.001*	< 0.001*	<0.001*			
Serum 25OHD (ng/mL)						
Pre 12 weeks	17.32±1.71	17.75±2.10	16.76±1.89	1	0.659	0.095
Post 12 weeks	20.35±1.75	24.33±2.37	18.64±1.94	<0.001*	0.002*	<0.001*
Within-group p-value	<0.001*	<0.001*	<0.001*			
Mean follicular size (mm)						
Pre 12 weeks	11.31±2.06	10.88±1.93	11.14±2.93	1	1	1
Post 12 weeks	21.34±2.04	17.77±2.05	15.05±2.85	<0.001*	<0.001*	<0.001*
Within-group p-value	<0.001*	<0.001*	<0.001*			

*=significant p-value, UVR=ultraviolet radiation, LAM=laser acupuncture maneuver, LH/FSH ratio=luteinizing hormone to follicle-stimulating hormone ratio, S.D.=standard deviation, PCOS=polycystic ovarian syndrome, P=probability, 25OHD=25-hydroxyvitamin D

the 3 studied PCOS groups as groups' Wilks' Lambda (Λ)=0.270, f =12.69, p -value<0.001, and η^2 =0.481; also, there was a statistically significant efficacy of applied treatments regarding the time (pre and post-assigned UVR, LAM, and metformin treatments) as Λ =0.005, f =254.163, p -value<0.001 and η^2 =0.995; finally, a reported significant impact of interventions at the interaction between time and the 3 studied PCOS groups as Λ =0.005, f =176.346, p -value<0.001 and η^2 0.928.

Discussion

Besides its role in decreasing patients' WC and BMI by stimulating abdominal acupoints that elevate the utilization of localized waist/abdominal fat for muscular energy⁹, the mechanism of LAM-induced improvement in LH, mean follicular size, FSH, and FSH may be explained by the modulation of factors involved in PCOS-associated hyperandrogenism. These factors are PCOS-induced hyper-activation of the sympathetic nervous system

and PCOS-induced overproduction of opioids (mainly β -endorphin). Stimulation of acupoints not only decreases the high levels of β -endorphin that inhibit sympathetic tone but also lowers PCOS women's ovarian androgen overproduction²⁰, regulates the ovulation process, and improves the size of follicles²¹.

In agreement with us, compared to adherence to lifestyle changes alone, adding LAM to lifestyle changes produced a greater decrease in BMI, LH, and LH/FSH ratio in addition to the greater increase in FSH and mean follicular diameter of women with PCOS¹⁸. Also, 3-month acupuncture significantly lowered PCOS women's LH, LH/FSH ratio, and BMI and increased their FSH²². In contrast to us, 16-week acupuncture did not improve PCOS women's LH, FSH, BMI, and LH/FSH ratio²³.

The significant effect of LAM on increasing 25OHD may aid in preserving bone quality and preventing osteoporosis by activating the pathways of osteoblastogenesis and angiogenesis, regulating/controlling the hypothalamic-pituitary-adrenal (gonadal) axis, attenuating the pathways of osteoclastogenesis, and inhibiting pro-inflammatory markers²⁴. Consistent with us, 6-month acupuncture in the elderly with primary osteoporosis significantly increased their bone metabolism indices such as osteocalcin (also termed bone Gla protein) and alkaline phosphatase²⁵.

Conversely, regarding the positive role of UVR in this study, humans are continuously subjected to different/variant levels of stimuli, such as UVR from the sun or artificial sources (such as artificial UVR lamps). Neuropeptides/neurotransmitters and neuroendocrine hormones are produced when UVR enters the human skin. These hormones – via activation of specific tiny molecules/micro-components – stimulate/trigger a skin-brain-gonadal axis. In experimental studies, stimulation of this axis after exposure to UVR-B may change hypothalamus-pituitary-

gonadal axis hormone levels, sexual responsiveness/attractiveness, ovarian size, and estrus duration/cycle²⁶.

The increased production of nitric oxide (NO) after exposure to UVR suppresses local accumulation of fats on adipose tissue, lowers excessive weight, increases insulin sensitivity, enhances glucose uptake/utilization, and corrects low levels of vitamin D¹³. Enhancement of these factors may explain the improvement of WC, 25OHD, and BMI in this study.

Supporting us, 582 sessions of UVR significantly improved the pregnancy rate, LH/FSH ratio, irregular rhythm of the menstrual cycle, LH, and PCOS-related symptoms (hirsutism and headache) in women with PCOS¹². In agreement with our results, long-term exposure to UVR is documented to increase postmenopausal women's FSH²⁷. Also, in healthy subjects, exposure to UVR increased levels of 25OHD²⁸. Contrary to us, 4-week UVR did not significantly alter the levels of LH and FSH, which may be due to the application of UVR on healthy subjects with normal FSH and LH levels²⁹.

Study limitations

Future PCOS trials must face this trial's limitation, loss to follow-up.

Conclusion

Adding LAM or UVR to metformin supplementation works better together for the improvement of PCOS symptoms.

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No funding for this PCOS study was received.

Conflict of interest

The authors of this AR study declare there is no conflict of interest.

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