Efficacy of Exercise Augmented with Ultrasonic Cavitation on Female Sex Hormones and Ovulation in Obese Polycystic Ovarian Women

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ABSTRACT

The current study was conducted to determine the efficacy of exercise augmented with ultrasonic cavitation on female sex hormones in obese polycystic ovarian women. Forty obese women with body mass index (BMI) > 30 Kg/m2, waist/hip ratio >0.80, were recruited in this study from the gynecology department, Kasr El-Aini University Hospital. Inclusion criteria were amenorrhea (no menses in the last 6 months) or oligomenorrhea (Less than four cycles in the last 6 months) and a typical ultrasonographic presentation of PCOS (multiple subcapsular follicles and thickened ovarian stroma) as well as LH / FSH ratio > 1.5. They were randomly divided into two equal groups: group A (Control group) composed of 20 patients who participated in exercise training program in addition to hypocaloric diet of 1200 kcal/day for four months, and group B (Study group) composed of 20 patients who received ultrasonic cavitation on the abdomen and the same exercise training program as well as hypocaloric diet of 1200 kcal/day for four months. All subjects of both groups were evaluated through assessment of BMI,WHR and bio chemical assay to measure female LH,FSH, and SHBG as well as ultrasonographic examination to assess ovulation and follicular growth before and after the course of treatment (4 months). The result of the current study revealed that PCOS women with abdominal obesity, who treated with ultrasonic cavitation added to exercise and diet showed a greater reduction of body weight and visceral fat. Theses changes were associated with a significant correction of the hormonal and menstrual abnormalities leading to a statistically significant (P<0.001) increase in the number of women who had normal ovulation and follicular growth in group (B) than those of group (A).

Key words: *Poly cystic ovarian syndrome, obesity, exercise, ultrasonic cavitation, hormonal changes.*

INTRODUCTION

Polycystic ovary syndrome (PCOS) is a common endocrine and metabolic disorder that occurs in 6 – 10% of women at the reproductive age[4,27]. It is associated with anovulation, infertility, hyperandrogenism, obesity and insulin resistance[34]. Endocrine characteristics of PCOS are elevated serum concentrations of androgens and Luteinizing hormone (LH) and decreased concentrations of sex hormone binding globulin (SHBG). The anovulation is associated with disturbance in the feedback from ovarian steroid hormones to the hypothalamus and pituitary, resulting in disturbances of the pulsatility of gonadotropin releasing hormone (GnRH)[38].

It has been suggested that the elevated concentrations of LH are due to an abnormal feedback by estrogens[14] and that the high tonic concentrations of LH in PCOS are detrimental to follicular growth[38]. The low concentrations of SHBG are associated with a relative increase in unbound concentrations of androstenedione and testosterone concentrations, which may further increase clinical expressions of hyperandrogenism, such as hirsutism[41].

Obesity is also seen and associated with insulin resistance and decreased SHBG as well as, in many cases, increased testosterone concentrations[43]. In addition, it results in increased rates of menstrual irregularities, infertility and miscarriage for those women who conceived[23]. Thus, obesity appears to be strongly related to affect the activity of hypothalmo-pituitary axis which causes excessive LH concentrations resulting in a lower chance of conception[39].

Obese women with PCOS have a characteristic distribution of a central pattern

of body fat known as android obesity in which fat deposited in the abdominal wall and visceral mesenteric area. This fat is more sensitive to catechol-amines and less sensitive to insulin[35]. In addition women with higher waist/hip ratios (i.e. more abdominal relative to hip fat) have higher total androgen and lower SHBG levels[36]. The increased androgen levels may directly affect insulin sensitivity in the target tissues, particularly the muscles, therefore contributing to the development of the insulin resistance state[2]. Obese women with PCOS need some long standing treatment to diminish their increased risk for endometrial cancer, hypertension and type II diabetes[5,8].

Traditional treatment in women with PCOS and anovulation is pharmacological induction of ovulation as antiestrogens which are effectives but have many side effects such as nausea, multiple pregnancy and ovarian hyperstimulation syndrome[11].

In obese POCS women, the first line of therapeutic option prior to any chemical treatment for induction of ovulation is weight loss[16] which helps to correct the clinical and endocrine abnormalities[13]. Weight loss is encouraged to ameliorate the metabolic consequences of PCOS, to improve spontaneous ovulation and to reduce the risk of spontaneous abortions following ovulation induction[1]. So many authors have recommended low caloric diet[22,25], exercise[30] and anti diabetic drugs[37] as an effective modalities for inducing weight loss in obese PCOS women.

Exercise, lipolysis and electric abdominal muscle stimulation can significantly reduce body weight and intra abdominal visceral fat in obese hypertensive women[24,42].

Various methods were reported to induce weight loss in obese PCOS women. But lack of studies investigate the effect of diet combined with either exercise or exercise augmented with lipolysis necessitated the need for more research in an attempt to reach to the most appropriate method for inducing weight loss and hormonal changes in obese PCOS women.

So, this study was specifically conducted to determine whether body weight and fat distribution changes via hypocaloric diet with exercise alone or in addition to ultrasonic cavitation could affect the hormonal profiles, ovulation and hence pregnancy rate in obese women with PCOS.

SUBJECTS, MATERIALS AND METHODS

Subjects

Forty obese women with body mass index (BMI) > 30 Kg/m^2, waist/hip ratio >0.80, between the ages of 23 and 31 years (mean 28.6 ± 1.3 years) were recruited in this study from the gynecology department, Kasr El-Aini, University Hospital.

Inclusion criteria were amenorrhea (no menses in the last 6 months) or oligomenorrhea (Less than four cycles in the last 6 months) and a typical ultrasonographic presentation of PCOS (multiple subcapsular follicles and thickened ovarian stroma) as well as LH / FSH ratio > 1.5.

In addition all women were free from any medical disorders as diabetes mellitus, thyroid dysfunction or concomitant cardiovascular, respiratory, renal and liver dysfunction and none of them was under hormonal treatment for at least 3 months prior to the start of the study or throughout the entire study period.

Patients with tubal adhesions as well as uterine abnormalities were also excluded from the study.

They were randomly divided into two equal groups: group A (Control group) composed of 20 patients who participated in exercise training program in addition to hypocaloric diet of 1200 kcal/day for four months, and group B (Study group) composed of 20 patients who received ultrasonic cavitation on the abdomen and the same exercise training program as well as hypocaloric diet of 1200 kcal/day for four months. Informed consent form had signed by each patient in this study.

Instrumentation

1- Weight-height scale for measuring the weight and height, then calculate the BMI in all groups.

2- Focused ultrasound device: Fat cavitation, BiCAVI (Ultimate), was used to apply the treatment procedure for all women in group (B).
3- Stationary bicycle ergometer (Model number E4.5) used for performing aerobic training for both groups (A&B).
4- Ultrasonic machine (Siemens Semolina SL 200, Serial number: SE00104) was used for measuring the follicular growth and ovulation.

Procedures

Evaluative procedures:

Initially a careful history was taken from each woman then the following evaluations were done for both groups.

* BMI and waist/hip ratio

Measurements of BMI in which the weight in kilograms divided by the square of the heights in meters and waist to hip circumference measured with a soft tape at the level of the umbilicus and the anterior superior iliac spine with woman in the standing position, were made before treatment and after the end of the study period (4 months).

* Biochemical assays

Blood samples were drown from an antecubital vein of each patient in the study at two occasions, firstly at the end at 2^{nd} or 3^{rd} day of the menstrual cycle after an overnight fasting just before starting her treatment regimen and secondly after 4 months of the treatment. It was centrifuged within 2 hours after withdrawal. Serum was stared at $-20^{O}C$ and assayed for LH and FSH with chemiluminescent enzyme immunoassay kits. Assays for fasting insulin by RIA kits and SHBG was determined by using an immunoradiometric assay (IRMA).

* Ovulation and follicular growth

It was done before and after the end of the treatment period for patients in both groups through abdominal sonographic examination with full bladder.

Treatment procedures:

All patients in both groups were followed the same hypocaloric diet of 1200 kcal/day for four months that contains high protient 50%, carbohydrate 30% and low lipid 20% as mentioned by Moran et al., 200332.

* Exercise training program

Each patient was participated in an exercise training program, three sessions per week for four months. Each exercise session was consisted of two programs of exercise training: I-Program of aerobic training for 40 minutes on a bicycle ergometer in which five minutes of warm up in the form of pedaling at 60 revolution per minute without load, thirty minutes of active pedaling with adjusted load to a chieve 60% of the patient predictive age of maximal heart rate (Maximal heart rate = 200- age of woman in years)31and ended the aerobic training session by five minutes of cool down as in warm up. The abdominal muscles were exercised for an additional 20 minutes by performing trunk sit ups (Crunches), lateral bends and rotation. The lower abdominal muscles were trained by bending both lower limbs toward chest as well as straight leg raising exercise.

Sustained muscle contraction for each specific exercise was maintained for five seconds followed by 10 seconds of relaxation. Each patient performed two sets of 10 repetitions per session for each specific exercise.

* Ultrasonic cavitation (Group B)

Before starting each treatment session, each woman in group (B) was instructed to evacuate her bladder to make sure that she was comfortable and relaxed throughout the treatment session.

From standing position, the abdominal area of each woman was divided transversally into 3 parts; Part I: from the xiphoid process to 3cm above the umbilicus, Part II: from 3cm above the umbilicus to 2cm below the umbilicus and Part III: from 2cm below the umbilicus to the pubic bone, and vertically each part was divided into right and left segments in relation to the linea alba, forming a total of 6 abdominal segments.

* Skin of the anterior abdominal wall was cleaned with alcohol then, a conducting medium (gel) was applied to the cavitational head of the ultrasound device, the device was turned on, the program of cavitation 40 kHz was chosen, the time was adjusted at 30 minutes and the intensity was adjusted at 50% in the first 6 sessions while it was adjusted at 75% at the last 6 sessions.

* Then the cavitational head was moved very slowly on each abdominal segment in a small circular movement for 5 minutes.
* After finishing the focused ultrasound of the 6 segments of the abdomen, the skin was cleaned with cotton.
* The total duration of the ultrasound treatment session on the 6 segments of the abdominal area was 30 minutes.

Statistical Analysis

Data were collected and statistically analyzed using the arithmetic mean, standard deviation student t test to compare groups before and after treatment as well as before and after four months of treatment in each group. A P value of <0.05 was a accepted as statistically significant.

RESULTS

At baseline, woman with PCOS in both groups were of similar age and primary infertility presented in 12 and 14 cases in group (A), (B) respectively and the remainder of them had secondary infertility.

Baseline BMI and waist/hip ratio and their changes alter are presented in table (1). In basal conditions, there was no difference in any of them between both groups. Changes in BMI and waist/hip ratio showed a significant reduction in BMI after treatment in both group (A and B). Whereas waist/hip ratio was significantly decreased after treatment only in group (B).

Table (1): BMI and WHR before and after treatment for both groups (A and B).

Variables		Group (A) Control group		Group (B) Study group	
		before	after	before	after
BMI (Kg/m^2)	Mean	33.76±2.51	29.21±2.91	32.10±2.39	28.72±2.22
	t value	22.25		31.73	
	P Value	< 0.01		< 0.001	
Waist/ hip ratio	Mean	88.98±2.83	86.97±5.05	88.01±3.91	85.7±4.91
	t value	0.93		7.29	
	P Value	> 0.05		< 0.05	

After completion of the treatment period about 70% of women resumed their regular menstruation in group (B) and 60% in group (A). The regular menstruation was significant increased in group (A) and (B) after treatment with favorite improvement in group (B), as shown in Table (2) and Fig. (1).

Table (2): Menstrual pattern before and after treatment in both groups (A and B).

Groups	Menstrual	Pre treatment (Number of women)	Post treatment (Number of women)	P value
Group (A)	Regular	2 (10%)	12 (60%)	< 0.05
	Oligomenorrhea	11 (55%)	6 (30%)	
	Amenorrhea	7 (35%)	2 (10%)	
Group (B)	Regular	3 (15%)	14 (70%)	< 0.05
	Oligomenorrhea	9 (45%)	4 (20%)	
	Amenorrhea	8 (40%)	2 (10%)	

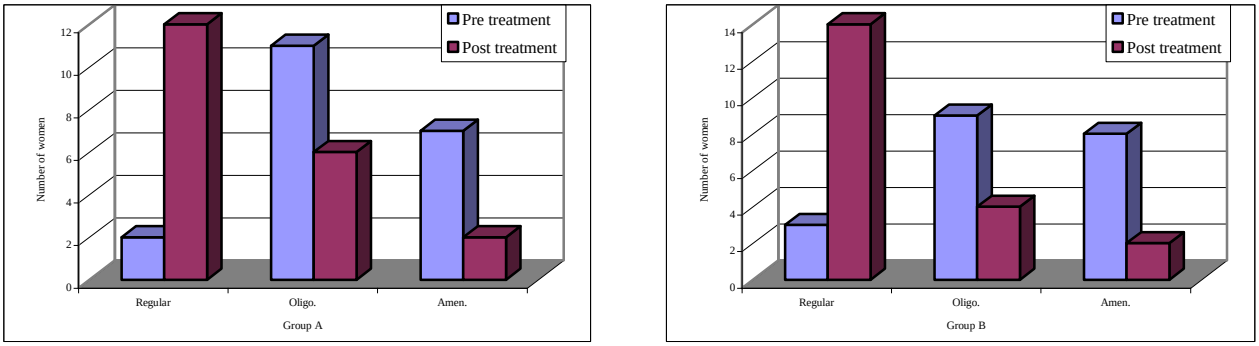

Fig. (1): Menstrual pattern before and after treatment in both groups (A and B).

At baseline, mean fasting insulin levels, LH, and LH/FSH ratio tends to be higher than normal limits and FSH and SHBG was lower than normal limits but without any significant difference between both groups. As a result treatment methods, there is a significant reduction in LH, LH/FSH ratio and fasting insulin and increase in FSH and SHBG in both groups (A and B). As a consequences changes in the hormones, seems to be decreased (LH, LH/FSH ratio and fasting insulin and increased FSH and SHBG much more in group (B) than in group (A) after completion of the treatment), Table (3).

Table (3): Hormonal profile in both groups before and after treatment.

Variables	Groups	Pre treatment	Post treatment	P value
LH (mIU/ ml)	(A)	9.4 ± 2.6	7.6 ± 2.3	< 0.05
	(B)	9.7 ± 2.2	7.1 ± 2.1	< 0.01
FSH (mIU/ ml)	(A)	5.3 ± 1.6	6.2 ± 1.5	< 0.05
	(B)	5.2 ± 1.3	6.6 ± 1.2	< 0.05
LH/ FSH ratio	(A)	1.8 ± 0.7	1.2 ± 0.6	< 0.05
	(B)	1.9 ± 0.5	1.07 ± 0.3	< 0.01
Fasting Insulin (µU/ ml)	(A)	19.5 ± 6.8	15.2 ± 5.3	< 0.05
	(B)	19.8 ± 5.7	15.1 ± 6.1	< 0.01
SHBG (ng/ ml)	(A)	3.4 ± 1.2	3.9 ± 2.1	< 0.05
	(B)	3.3 ± 1.1	4.2 ± 1.9	< 0.01

LH : Latinizing hormone. FSH: Follicular stimulating hormone. SHBG: Sex hormone binding globulin.

As a result of the weight loss program and its effects for improving the hormonal profiles specially in group (B) than (A), the number of women regained their normal ovulation and optimal follicular growth was 10, 13 women in group (A) and (B) respectively after the end of treatment, table (4).

The comparison between groups showed a statistically significant (P<0.001) increase in the number of women who had normal ovulation and follicular growth in group (B) than group (A).

Table (4): Ovulation, follicular maturity in both groups after treatment.

Groups	Ovulation (Number of women)	Follicular growth (mm)
Group (A)	10 (50%)	19.9 + 3.2
Group (B)	13 (65%)	21.2 + 3.3
Difference	3 (15%)	1.30+ 0.01
P value	< 0.001	< 0.001

DISCUSSION

Dietary induced weight loss may represent an appropriate means of improving hyperandrogenism and all parameters of the metabolic syndrome in obese PCOS women[22,26].

The amelioration of hyperinsulinemia and insulin sensitivity may explain these biological effects together with concomitant improvement of related clinical

manifestations. However, available studies agree in suggesting that even minimal changes in body weight could reduce the insulin levels, which can be achieved by low caloric diet with or without exercise, may be sufficient, in many cases, to reduce increased androgen even after short term administration[30,36].

The pathogenetic role of obesity and body fat distribution in PCOS is still a matter of intensive debate. Available data seem to support the concept that PCOS and abdominal obesity may have an additive effect or a synergistic, negative impact on insulin sensitivity[7]. In addition, others found that women with POCS may not be insulin resistance in the absence of increased abdominal fatness[18]. Thus the relative excess of insulin or enhanced ovarian sensitivity to insulin with an elevated LH leads to thecal hyperplasia, increased androgen secretion, arrest of follicular development and therefore an ovulation, with menstrual disturbance[19].

So, this study was specifically conducted to determine whether body weight and fat distribution changes via hypocaloric diet with exercise alone or in addition to ultrasonic cavitation could affect the hormonal profiles, ovulation and hence pregnancy rate in obese women with PCOS.

The results of the present study proved that hypochlorite diet with exercise and ultrasonic cavitation produced a significant reduction in body weight and visceral fat which changes significantly all the abnormal hormones by reducing fasting insulin, LH and LH/ FSH ratio and increasing FSH as well as SHBG and ovulation in obese women with PCOS after 4 month of treatment. Also, it represented that exercise combined with ultrasonic cavitation is an effective method in reducing weight, abdominal fat and treating such cases. These results appear to justify the opinions regarding the effectiveness described in the study of Irving et al., (2008)[21], who reported that High-Intensity Exercise Training (HIET) significantly reduce total abdominal fat ($P<0.001$), abdominal subcutaneous fat ($P=0.034$) and abdominal visceral fat (AVF) ($P=0.010$). And they concluded that body fat changes are affected by the intensity of exercise training.

Also, Vispute et al. (2010)[44] reported that when a muscle contracts involntrly, the chemical changes taking place within the muscles are similar to those associated with voluntary contractions in normal exercising. These chemical reactions which results from muscle contractions utilize glycogen fat and other nutrients stored in the muscles. Other explanation about the effect of lipolysis was mentioned by Kanter and Alon, (1994)[25] who reported that muscle contraction stimulates the adrenergic interstitial nerve endings that liberates more catecholamine hormone which enhance the adenilate cyclase to convert adenosine triphosphate to cyclic adenosine monophsphate thus activating lipasis.

The results of ultrasonic cavitation with exercise may be explained by (Enrico, 2008)[9] who concluded that 'to get rid' of the blood fatty acids resulting from the locally treated adipocytes with ultrasound, some aerobic exercise is required to be performed within 60 minutes after the ultrasound treatment.

Unfortunately any further comparison regarding the effects of ultrasonic cavitation on weight loss in PCOS is difficult because there are no studies curried out.

On following hypocaloric diet , women with the abdominal obesity phenotype respond better than those with peripheral type[8], it could have been expected that when cavitation is combined with a hypocaloric diet, the weight loss could be greater. In addition ultrasonic cavitation favored a greater reduction of the waist/ hip ratio, which suggest a significant modification of the pattern fat distribution, particularly at the abdominal level. This reduction in regional fat distribution could contribute to the effect of cavitation in improving the hormonal profiles in obese women with PCOS.

Interestingly in (2000), Butzow et al.,[3] confirmed and agree with that of Harless et al. (1984)[15] in which they concluded that weight reduction with low caloric diet in severally over weight infertile women results in a decrease LH concentration, a reduction in LH/ FSH ratio and FSH predominance favoring follicular genesis.

While the combination between low caloric diet with exercise in this study showed

an obvious improvement in the hormones with higher ovulation rate which supported by the study of Hollman et al. (1996)[17].

The present results concerning the effect of exercise on the female sex hormones (FSH, LH and LH / FSH ratio) were supported by the work of Hollman et al. (1996)[17] who found that FSH increased with exercise. Also, Huber-Buchholz et al. (1999)[20] reported that exercise program resulted in 39% reduction in LH levels which cause a restoration of ovulation in treated overweight, infertile women.

The results of this study for exercise agree again with those reported by Kraemer et al., (1999)[28] which demonstrated that aerobic exercise three times / week for 12 weeks results in a significant reduction in body mass and fat mass. In addition Evans et al., (1999)[10] found that aerobic exercise at 50% of maximal oxygen consumption results in weight reduction by a means of 3.9±3.4 Kg and decrease in the percentage of body fat by 2.5%.

Galletly et al. (1996)[12] mentioned that program of a regular exercise and developing healthy eating patterns can produce considerable improvement in the outcome of treatment for infertility in obese women. During aerobic exercise, nonesterified fatty acids constitute an important fuel oxidized by working muscles. The nonesterified fatty acids are released into the circulation as a product of triacylglycerol hydrolysis in the adipose tissue. This lipolysis is a key step in the metabolic process leading to the decrease of fat mass. Lipolysis is mainly regulated by catecholamines that are lipolytic through α-adrenoceptors and antilipolytic through insulin and β adrenoceptors[29]. Increasing the sensitivity of adipose tissue to lipolytic action of catecholamines can facilitate lipid mobilization from fat stores. Aerobic exercise training modifies adipose tissue lipolysis through enhancement of α-adrenergic response and decrease in the adipocyte antilipolytic activity[6] and reduced fasting insulin concentration[16]. Also, the addition of exercise to hypocaloric diet is advocated to counteract the negative metabolic adaptations that occur during caloric restriction because exercise prevents declines in fat oxidation[33].

Locus et al. (1998)[30] and Shangold (1997)[40] reported that the stress of the exercise reduce LH pulse frequency, thus exercise energy expenditure alone can reduce energy availability to suppress LH pulsitility which can be followed by reduced androgen production.

In summary, this study shows that PCOS women with abdominal obesity, who treated with ultrasonic cavitation added to exercise with low caloric diet in comparison with exercise added to low caloric diet, induced a greater reduction of body weight and visceral fat. Theses changes were associated with a more significant correction of the hormonal and menstrual abnormalities as well as increased the possibility of occurrence of pregnancy in comparison with exercises added to low caloric diet.

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الملخص العربي

فعالية التمرينات المحفزة بالتجويف عن طريق الموجات فوق الصوتية على الهرمونات الجنسية الأنثوية والتبويض في النساء البدينات المصابات بمرض تكيس المبيض

أجريت هذه الدراسة لتحديد مدى فعالية ممارسة التمرينات المحفزة بالتجويف عن طريق الموجات فوق الصوتية على الهرمونات الجنسية الأنثوية والتبويض في النساء البدينات المصابات بمرض تكيس المبيض وشاركت في هذه الدراسة 40سيدة بدينة تعانين من مرض تكيس المبيض تم اختيارهن من قسم أمراض النساء والتوليد بمستشفى القصر العيني وكانت كل منهن تعانى من انقطاع الطمث (عدم وجود الحيض في آخر 6 أشهر) أو ندرة الطمث (أقل من أربع دورات في ال 6 أشهر الأخيرة) وكانت نسبة الهرمونات FSH /LH اكبر من 1.5 . وتم تقسيمهن عشوائيا إلى مجموعتين متساويتين المجموعة A (المجموعة الضابطة) تتكون من 20 مريضة قمن بممارسة التمرينات العلاجية بالإضافة إلى الالتزام ببرنامج غذائي منخفض السعرات وذلك لمدة أربعة اشهر والمجموعة B (مجموعة الدراسة) وتم علاجهن بالتجويف عن طريق الموجات فوق الصوتية بالإضافة إلى نفس التمرينات العلاجية والبرنامج الغذائي منخفض السعرات لمدة أربعة اشهر . وقد تم تقييم جميع المريضات في المجموعتين قبل وبعد الدراسة من خلال قياس مؤشر كتلة الجسم ونسبة محيط الخصر إلى الحوض وكذلك عن طريق قياس نسبة LH، FSH، وSHBG في الدم وكذلك الفحص بالموجات الصوتية التشخيصية لقياس التبويض ونمو البويضة .
وكشفت نتائج الدراسة الحالية أن النساء البدينات المصابات بتكيس المبيض اللاتي تم علاجهن بواسطة التجويف بالموجات فوق الصوتية إضافة إلى ممارسة التمرينات أظهرن انخفاضا أكبر في وزن الجسم مما أدى إلى تصحيح نسب الهرمونات الأنثوية ومعدلات الدورة الشهرية كما أظهرت هذه المجموعة زيادة ذات دلالة إحصائية (P <0.001) في التبويض وكذلك نمو البويضات أكثر من المجموعة الضابطة اللاتي تم علاجهن بواسطة التمرينات العلاجية فقط .
الكلمات الدالة: تكيس المبيض ، السمنة، التمرينات العلاجية ، التجويف بالموجات فوق الصوتية، التغيرات الهرمونية .