Original Article

Comparison between the Effects of Different Frequencies of Ultrasonic Cavitation on Abdominal Adiposity and Female Hormones In Polycystic Ovarian Syndrome

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Abstract

Aim To determine if there is a difference between the effect of 26000HZ ultrasonic cavitation and 40000HZ ultrasonic cavitation on abdominal fats and feminine sex hormones in PCOS. **Design** Randomized Controlled Trial. **Materials and Methods** 30 women diagnosed with PCOS were involved in this study. Their BMI_s were 30 to 35 kg/m², ages were 20 to35 yrs., LH/FSH ratio was ≥ 1.5 and waist/hip ratio was > 0.85. They were randomly distributed into group A (n=15) treated by 40000HZ ultrasound cavitation, and group B (n=15) treated by 2600HZ ultrasound cavitation for 8 weeks. Each session was 30 minutes, 3 times/week. All women of both groups applied healthy diet with 1200 kcal/day. All women had been assessed by measuring weight, height, BMI, hip and waist circumference, WHR, LH, FSH level in the blood, and LH/FSH ratio. **Results** revealed a highly significant decrease in post-testing mean value of the waist circumference, hip circumference, Waist- hip ratio (WHR), weight, BMI, and post-testing median value of LH/FSH ratio in both groups ($p < 0.0001$) while there was a significant increase in mean value of FSH post-treatment in both groups ($p < 0.05$). LH level post-treatment revealed a statistically significant decrease in group B only ($p < 0.05$). Moreover, a significant differences were found in mean values of WHR, F.S.H, and median value of LH/FSH ratio in favor of group (B) than group (A) ($p < 0.05$). **Conclusion** Both 40000 HZ and 26000HZ ultrasound cavitation were capable of improving abdominal obesity and hormonal disturbance and can be used as intervention programs for women with PCOS. Also, PCOS women may get additional benefits in improving their WHR, FSH level, and LH/ FSH ratio through 26000HZ ultrasound cavitation more than 40000 HZ ultrasound cavitation.

Keywords: Cavitation ultrasound therapy, Obesity, PCO, Body contouring.

INTRODUCTION

Infertility affects 8-12 percent of reproductive-age women (1). There are numerous causes for this deterioration in health; however, Polycystic Ovarian Syndrome (PCOS) is an endocrinal disturb and is the dominant cause of infertility, affecting 6-10% of reproductive aged women (2) and persisting throughout women's lives due to its endocrine nature (3).

There is no doubt that obesity is strongly related to ovarian cysts; roughly 60% to 70% of PCOS cases suffering from obesity, in particular trunked obesity, where abdominal fat thickness and waist-to-hip ratio are high. Insulin resistance and concomitant hyperinsulinemia, which precipitate hyperandrogenism in women with PCOS, may be exacerbated by obesity, particularly abdominal adiposity. (4).

Weight loss is the primary interventional strategy in obese women with anovulation or PCOS because even a 5% weight loss improves menstrual regularity, fertility, clinical, endocrinological, and by reducing androgen and insulin concentrations and enhancing insulin sensitivity, a considerable majority of affected women's hyperandrogenic traits are alleviated. (5).

To manage obese persons, several strategies have been developed, including food therapy, exercise, medication, and surgery (6). There are various non-invasive body sculpting technologies available nowadays. One of these methods is USFC, which employs concentrated ultrasound waves to pass deep heating into subcutaneous fatty tissues (7). Ultrasound-focused Cavitation (USFC) is a relatively new non-invasive method of eliminating fat and sculpting a specific portion of the body. It is an improvement on the Vibro-liposuction procedure (surgical liposuction using ultrasound energy at the end of a probe that is inserted into the middle of the fat layer). Vibro-liposuction is called refinement because it is an intrusive procedure that inserts a foreign instrument into the body, increasing the danger of infection and causing fat emboli in the blood vessel system, as well as bleeding problems. USFC, on the other hand, uses ultrasonic energy with maximum power while avoiding the embedding of unusual items. It is applied to the skin's surface where the target fat layer is located (8). Many negative effects of body contouring surgery, medication, or other modalities have been recorded, therefore this study was done to approach body contouring from a safer, more effective, and less intrusive perspective. Furthermore, preliminary preclinical and clinical investigations have shown that USFC is effective for subcutaneous fat layer reduction (9, 10). However, the best effective frequency for USFC is still unknown (9, 10, 11). As a result, there was a need to evaluate impact of various frequencies of ultrasonic waves on abdominal fats. This was the first study to compare effects of two different ultrasonic cavitation frequencies on abdominal fats and sex hormones in obese women with poly ovarian cysts.

MATERIALS AND METHODS

Design

A randomized controlled trial.

Recruitment

Thirty non-gravid women had participated in this study. All of them diagnosed with PCOS and suffering from infertility for one year at least. They were called up from outpatient gynecological clinic at Minya Governorate Hospital in Minya, Egypt, and were assigned randomly into two equal groups by computer-generated randomization process. In April 2018, the research ethical committee of faculty of physical therapy-Cairo University certified the study (NO.P.T.REC/012002854). Also, it was registered at clinical trials (NCT05039125) in Sep. 9, 2021). After discussing the nature, purpose, and advantages of the study, each participant provided informed consent.

The inclusion and Exclusion criteria

30 women diagnosed with PCOS were involved in this study. Their BMIs were 30 to 35 kg/m², ages were 20 to35 yrs., waist/hip ratio was > 0.85 and LH/FSH ratio was ≥ 1.5. They were randomly distributed into group A (n=15) treated by (40000 Hz) ultrasound cavitation and group B (n=15) treated by (2600 Hz) ultrasound cavitation for 8 weeks. Each session was 30 minutes, 3 times/week. All women of both groups applied a low caloric diet (1200 kcal/day). Exclusion criteria was hypertension, diabetes mellitus, liver or kidney diseases, heart diseases, high cholesterol, pregnancy, skin diseases or hernias in abdomen.

Outcome measures

Anthropometric measures

By weight-Height scale which used for all women of group (A) as well as group (B) before start and after end of treatment program (8 weeks), to measure weight, height and estimate BMI. Also, all women in both groups had their waist and circumference measured with a tape measure to compute their waist/hip ratio (12).

Data recording sheet

Each participant's data and information were recorded in a recording datasheet, including personal, past, and detailed medical and obstetrical histories, to confirm that there was no heart disease, diabetes mellitus, high cholesterol, liver and kidney disease, pregnancy, hypertension, and skin diseases or hernias in abdominal area.

Laboratory investigation

A 5cm venous blood sample was drawn from the antecubital vein in the forearm of each participant in both groups at 10 a.m. on two occasions: once at the conclusion of the second or third day of her menses following an overnight fast prior beginning treatment, and once after end of program. Within 2 hours of being removed, it was centrifuged. Serum was stored at -20°C before and after treatment to assess FSH and LH level (13).

Treatment procedures

All women in study were instructed to implement a healthy diet with 1200 calorie per day. according to their requirements (15% fat, 55% carbs, and 30% protein) (11).

- Each women in both groups was gave a detailed explanation about treatment techniques.
- Each woman asked for drink at least 3 liter of water after each treatment sessions to help lymphatic drainage.

- Each woman was informed to evacuate her bladder immediately before start each session to be relaxed and comfortable all through the session.
- The abdomen for each woman while standing was divided vertically by linea alba into right and left segments, and horizontally into three zones; upper zone: from xiphoid process to 2cm superior to umbilicus, mid zone: 2cm above the umbilicus to 3cm below it, and lower zone: from 3cm below the umbilicus to upper border of pubic bone. Fig. (1).

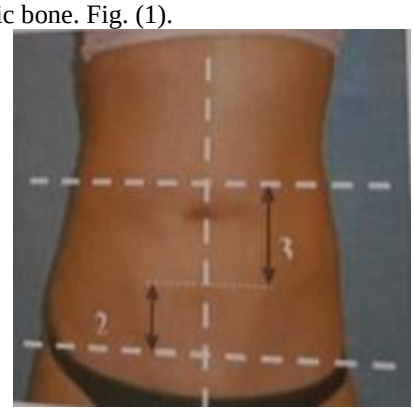

Fig. (1) divisions of abdominal segments**.**

- The skin of abdomen wiped with alcohol and gel was put as conducting medium to ultrasonic waves. Then a circular massage was applied by head of cavitation for 5 minutes per each segment for a total of 30 min for all six abdominal segments, 3 times/week for 8 weeks. Group (A) treated by 40000 HZ ultrasound while group (B) received 26000 HZ ultrasound

Statistical Analysis

Descriptive statistical analysis was used to obtain data. All normally and non-normally distributed data were presented as mean SD or median (IQR). The Manne-Whitney U test was used to compare non-normally distributed data (LH/FSH ratio) between the two groups, and the paired t-test was employed to examine data with a normal distribution before and after the intervention. To compare regularly distributed data between groups, the "unpaired t-test" was utilized, whereas the Wilcoxon test was employed to examine non-normally distributed data (LH/FSH ratio). Significance level was p 0.05. The statistical software for social studies version 25(SPSS) was used to perform all statistical analyses (SPSS, Inc., Chicago, IL).

RESULTS

Table (1) Mean values of physical characteristics of participant women of both groups (A and B) at baseline.

Items	Group (A)		Group (B)		comparison		S
	Mean	±SD	Mean	±SD	t-value	p-value	
Age (years)	27.93	±2.92	27.12	±2. 69	0.823	0.42	NS
weight (Kg)	78.03	±6.89	82.06	±4.72	-1.947	0.06	NS
Height (cm)	155.07	±4.25	158.65	±3.10	-.595	0.556	NS
BMI (kg/m^2)	32.39	±1.52	32.58	±1.23	-0.390	0.70	NS
Waist circumference (cm)	105.30	±6.16	106.59	±6.05	0.596	0.56	NS
Hip circumference (cm)	118.93	±5.22	122.41	±6.51	1.653	0.11	NS
Waist/Hip ratio	0.88	0.03	0.87	0.01	1.805	0.08	NS

Table (2) inter and intragroup comparison between mean values of W, BMI, WC, HC, WHR, FSH and LH at both groups measured at pre-and post-treatment.

		Group A	Group B	MD	t-value	P value	s
Weight (Kg)	Pre Mean±SD	78.03±6.89	82.06±4.72				
	Post Mean±SD	71.57±6.46	73.44±5.03	-1.87	-0.922	0.36	NS
	MD	6.46	8.62				
	% Changes	8.28↓	10.50↓				
	t-value	20.101	24.459				
	P value	0.0001*	0.0001*				

Body mass index (BMI) (kg/m2)	Pre Mean±SD	32.39±1.52	32.58±1.23				
	Post Mean±SD	29.60±1.46	29.16±1.49	0.45	0.858	0.40	NS
	MD	2.79	3.42				
	%Changes	8.61↓	10.50↓				
	t-value	18.304	24.947				
	P value	0.0001*	0.0001*				
Waist circumference (WC)cm	Pre Mean±SD	105.30±6.16	106.59±6.05				
	Post Mean±SD	101.27±6.62	99.94±6.41	1.33	.575	0.57	NS
	MD	4.03	6.65				
	%Changes	3.82↓	6.24↓				
	t-value	9.579	31.803				
	P value	0.0001*	0.0001*				
Hip circumference (HC) cm	Pre Mean±SD	118.93±5.22	122.41±6.51				
	Post Mean±SD	116.80±5.28	118.88±6.60	-2.08	-.976	0.34	NS
	MD	2.13	3.53				
	%Changes	1.79↓	2.88↓				
	t-value	7.794	4.542				
	P value	0.0001*	0.0001*				
Waist-hip ratio (WHR)	Pre Mean±SD	0.88±0.03	0.87±0.01				
	Post Mean±SD	0.87±0.04	0.84±0.03	0.03	2.306	0.03	S
	MD	0.01	0.03				
	%Changes	1.13↓	3.45↓				
	t-value	4.272	4.519				
	P value	0.001*	0.0001*				
Serum Follicular stimulating hormone(FSH) level	Pre Mean±SD	4.82±1.28	5.03±1.22	-0.21	-0.473	0.64	NS
	Post Mean±SD	6.70±1.23	7.68±1.38	-0.98	-2.113	0.04*	S
	MD	-1.88	-2.56				
	%Changes	39 ↑	52.86↑				
	t-value	-8.005	-19.332				
	P value	0.0001*	0.0001*				
Serum Luteinizing hormone (LH) level	Pre Mean±SD	12.51 ±1.91	13.05±2.42	-0.54	-0.694	0.49	NS
	Post Mean±SD	11.99±1.97	12.13±2.21	-0.14	-0.183	0.86	NS
	MD	0.52	0.92				
	%Changes	4.15 ↓	7.05↓				
	t-value	1.250	5.376				
	P value	0.232	0.001*				

Table (3) inter and intragroup comparison between median values of LH/FSH ratio level at both groups measured at pre-and post-treatment

LH/FSH ratio	**Pretest**	**Post-test**	**Difference**	**% of change**	**Z-value**	**p-value**
	Median (min.-max.)	**Median (min.-max.)**				
Group (A)	2.61 (1.96-3.79)	1.77 (1.51-2.25)	0.84	32.18↓	3.351	0.001* (HS)
Group (B)	2.76 (1.86-3.46)	1.54 (1.31-2.20)	1.22	44.20↓	3.621	0.0001*(HS)
Difference	-0.15	0.23				
Z-value	-0.067	2.021				
p-value	0.94(NS)	0.04(S)				

DISCUSSION

Obesity, particularly the abdominal phenotype, is frequent in PCOS and exacerbates many of its reproductive and metabolic features. Weight loss, even modest weight loss of 5% of body weight, had been shown to be an effective way of improving reproductive and metabolic state in PCOS women (14). Few studies had been conducted to search the impact of USFC on abdominal obesity in PCOS women. Furthermore, there was a knowledge gap about the most effective frequency for USFC, which demonstrated a significant disparity between research (9,10, 11). As a result, there was a need to evaluate impact of various ultrasonic frequencies on abdominal fats. As a result, this study was imposed in order to contribute fresh clues to the field of physical therapy.

In terms of anthropometric measurements, According to our findings, a substantial drop was found in mean value of weight, BMI, waist circumference, hip circumference, and WHR in both groups (A and B). When the findings of both groups were compared, it was discovered that there was a substantial improvement in the post-testing mean values of WHR in favor of group (B) than group (A)

The significant decrease in BMI in both groups in this study could be based on certain mechanisms, as diuresis and glycogen running out. Fat mass depletion enhanced by focused ultrasound through activating lipoprotein lipase (LPL) which cracks triglyceride into free fatty acid (FFA) and glycerol resulting in weight loss. The lipolytic range of USFC is 20-70 kHz (low-frequency wave), which explains the significant weight loss in both groups. Furthermore, a decrease in central fat mass may explain the decrease in waist circumference, hip circumference, and WHR. FFA are mobilized from centrally distributed adipose tissue as a result of high LPL activity (11). Fat removal is then accomplished by the lymphatic, venous, or immune systems (15).

Furthermore, the adoption of a regular balanced low calorie diet for both groups that delivered 1200 kcal daily, according to each participant's requirement (15% fat, 55% carbs, and 30% protein) contributed to BMI decrease. Previous research found that a three-month diet regimen resulted in a 10% reduction in body weight (11).
These findings were consistent with those published in perimenopausal obese women by Sabbour et al. (11) who found that a low-calorie diet with cavitation ultrasonic therapy decrease abdominal fats in obese perimenopausal women. Younis et al. 16 validated and contributed solid evidence that low-frequency ultrasound is an effective modality in local fat reduction according to the current study's findings.

Also, Naeimi et al. (17), concluded that ultrasonic cavitation is an excellent tool for destroyed abdominal extra subcutaneous fats, as shown by a drop in skinfold and waist measures among individuals.
Saedi and Kaminer (18) validated the current study's findings by observing a 2 cm less in belly contour following a single treatment of ultrasonic cavitation. Furthermore, our findings were emphasized by those of Ascher et al. (19), who confirmed that cavitation therapy is a convincing non-invasive tool for local fat management, as evidenced by 3.58 cm loss in waist circumference after treatment.

The outcomes of this study showed significant decline in median value of LH/FSH ratio post-treatment in both groups, as well as a significant increase in mean value FSH post-treatment in both groups. LH levels in group B reduced statistically considerably following medication, however there was no significant decrease in group A. When the findings of both groups were compared, it was discovered that there was a significant improvement in post-testing mean values of FSH and median value of the LH/FSH ratio in favor of group (B) over group (A).
The current study's hormonal improvement in both groups could be explained by the fact that weight loss in overweight women with PCOS is a successful plan of repairing endocrinological, metabolic and reproductive parameters in PCOS women. Furthermore, the significant drop in WHR reflects a positive change in fat distribution pattern, particularly in the abdomen. This shift in regional fat distribution may contribute to cavitation's ability to improve hormonal profiles in obese PCOS patients (14).
Mekawy and Omran (13) as well as, Hamdy et al. (20), proved that ultrasonic cavitation had a positive effect on ovulation and sex hormones in PCOS women through reduction of abdominal fat thickness and general weight loss.

This is the first study to compare 40000HZ ultrasonic cavitation and 26000HZ ultrasonic cavitation and found a significant difference in mean values of WHR, F.S.H, and LH/FSH ratio in favor of group (B) than group (A). Rather, earlier studies solely looked at the influence of either 4000 HZ or 26000 HZ frequencies, without comparing them. It appears acceptable to draw those conclusions for a variety of reasons, including the fact that the lower the frequency of USFC, the greater the penetration and lower the attenuation. When an ultrasound wave travels through tissue, it is attenuated by scattering and absorption, and is converting to heat. Attenuation increases in a linear fashion with frequency. As a result, lower frequencies have less attenuation and higher penetration (21).
All of the aforementioned points to the effectiveness of USFC (with both frequencies 40000 HZ and 26000 HZ) to improve hormone levels and abdominal obesity in women with PCOS.

Conclusions and Clinical Implication

Both 40000 HZ and 26000 HZ ultrasonic cavitation were capable of alleviating abdominal obesity and hormonal disruption and might be employed as intervention programs for women with PCOS. Furthermore, PCOS women may benefit more from employing 26000 HZ ultrasonic cavitation than 40000 HZ ultrasound cavitation in improving their WHR, FSH level, and LH/ FSH ratio.

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Conflict of interest
No conflict.

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