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EFFECT OF ULTRASONIC CAVITATION ON ABDOMINAL OBESITY IN ADOLESCENT FEMALES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT:

Background: Abdominal obesity is associated with higher metabolic syndrome burden in adolescent population especially in females**.** Focused pulsed ultrasound cavitation technology reduces localized subcutaneous adipose tissue.

Objective: to determine the effectiveness of ultrasonic cavitation on abdominal obesity in adolescent females.

Methods: Fifty volunteer females with abdominal obesity participated in this study. Their age ranged between 17-21 years and their BMI ranged from 30–35 kg/m^2. They were collected from physical therapy outpatient's clinic of modern university for technology and information in Cairo. They were subdivided randomly according to enclosed envelop into two equal groups. Group (A) consisted of 25 females who received ultrasonic cavitation on the abdominal region for 30 minutes as well as aerobic exercises through treadmill using moderate intensity (12–14, according to Borg scale) for 30 minutes, 2 times per week for 6 weeks and low caloric diet plan; group (B) consisted of 25 females who performed aerobic exercise and low caloric diet plan as in group (A). The females in groups (A and B) were evaluated through the body fat analyzer, the tape measurement and the skin fold caliper.

Results: This study revealed that there was a statistical significant difference in mean values of weight, body mass index, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat post treatment in both groups and the favor in significant reduction is to group A.

Conclusion: Ultrasonic cavitation in conjunction with aerobic exercises and low caloric diet was effective in decreasing the weight, BMI, the waist circumference, the fat thickness, the waist-hip ratio, the percentile body fat and trunk fat and leading to maintain a graceful appearance and self-confidence for female in adolescent period.

Key words: Ultrasonic cavitation, Aerobic exercises, Diet plan.

I. INTRODUCTION

Obesity is a disease marked by excessive adiposity that causes significant morbidity and mortality as a result of weight-related consequences. As a result, the diagnostic evaluation should include an anthropometric measure that shows increased fat mass as well as an indicator of how much the excess adiposity is harming the patient's health. [1]. Obesity, which may begin as early as childhood, may reach a peak in severity throughout adolescence; from a practical standpoint, it is critical for adolescents to comprehend the physiological processes that affect them. The advantages (e.g., growth spurts, increased fat-free mass (FFM) and, as a result, greater energy consumption and demands) and the disadvantages (e.g., raising body fat in girls) of changes in pubertal body composition can help adolescents to be more aware in maintaining their healthy weight [2]. Overweight and obesity were found to be prevalent among Egyptian adolescents at 20% and 10.7%, respectively. [3].

Environmental factors, lifestyle preferences, and the cultural background all play an axial role in the global obesity epidemic. Obesity and overweight are thought to be the outcome of increased calorie and fat intake in general. On the other side, there is evidence that excessive sugar intake from soft drinks, larger portion sizes, and a persistent reduction in physical activity have all contributed to rising obesity rates around the world, particularly among adolescents. [4]**.**

In the adolescent population, abdominal obesity is linked to a higher metabolic syndrome burden. Obesity, particularly abdominal obesity, was highly common, especially among women. [5, 6]**.** Obesity requires multifaceted treatment techniques, and it may be necessary to continue treatment for the rest of one's life. Weight loss of 5 percent to 10 percent can significantly enhance an individual's quality of life, health and financial cost, as well as a country's overall economic burden [7]**.** Obesity and overweight were found to be prevalent in 23% and 14% of the girls, respectively. Central obesity was found to be prevalent in 26% of the population. In the normal weight group, around 14% of the girls were centrally obese [8]**.**

Obesity treatment should shift its focus from weight loss to weight management, which entails obtaining the best weight attainable while maintaining overall health. Weight management is described as the strategy of eating and exercising in a healthy and long-term manner to reduce disease risk and promote feelings of energy and well-being. [9]. In today's aesthetic surgery, fat reduction and body shaping surgeries have become widespread commodities. Despite the fact that liposuction is quite effective in removing significant quantities of excess fat, surgery comes with a high complications risk and severe side effects. The post-procedural discomfort, hematoma, delayed recovery, infection, edema, bruising, or scarring are all possible complications. [10]. Currently, a variety of therapeutic approaches are being employed to safely reduce the volume of subcutaneous fat deposits and assist obese ladies in achieving a more appealing body shape and contour [11]**.** Focused pulsed ultrasound cavitation, cryolipolysis, low-level laser therapy, and radio frequency ablation are the four most popular noninvasive procedures for minimizing regional subcutaneous adipose tissue. [11]. The targeted adipocytes are mechanically disrupted, destroyed, and naturally sequestered using focused pulsed ultrasonic cavitation technology [12]**.** During treatment, focused ultrasound is used to produce bubbles between adipocytes in the targeted location by causing rapid changes in interstitial fluid pressure. The rapid pressure changes cause these bubbles to implode, rupturing the adipocyte walls and ultimately eliminating the targeted fat cells. The triglycerides and cellular debris generated by the damaged adipocytes are processed by the body's physiological and metabolic pathways before being excreted [12].

Aerobic exercise improves fat metabolism by boosting oxygen delivery (through blood flow) and extraction (through capilarization), allowing the cell to more efficiently oxidize (burn) fat [13]. Increasing energy expenditure can hasten fat loss by producing a negative energy balance, altering body composition, and potentiating the maintenance of those changes [14]. Dieting is commonly practiced for loss of weight, particularly within women, also it is serious health issue since it can lead to disordered eating in those who are vulnerable. A Low caloric diet result in a weekly weight loss of 0.5–1 kilogram when provided an energy deficit of 500–1000 calories daily and a total dietary calorie intake of 800–1500. [15]**.**

As a result, the study's primary aim of was to determine the effectiveness of ultrasonic cavitation on abdominal obesity in adolescent females.

II. PARTICIPANTS AND METHODS

Study design:

Randomized controlled trial, approved from Institutional Review Board of Faculty of Physical Therapy, Cairo University, prior conducting study (no: P.T.REC/012/002357) and clinical trial registration in Clinicaltrial.gov with an identifier number NCT04930068. The study followed Declaration of Helsinki guidelines on conduct of human research.

Participants

Overall, fifty females diagnosed as abdominal obesity they were collected randomly from physical therapy outpatient's clinic of modern university for technology and information between September and December 2020. Their age ranged between 17-21 years and their BMI were ranged from 30–35 kg/m^2. Detailed medical history was obtained for all participants to screen other pathological conditions that may affect the study as cardiac, vascular or skin diseases. Exclusion criteria of the study were as follows: mental health problem such as

depression and anxiety, females with BMI exceed 35kg/m^2, females have cardiac or vascular diseases, females carry pacemaker and skin disease interferes with cavitation application. All females were single, there waist circumference was >80cm, there waist hip ratio was >0.85 and all females took low-caloric diet plan (1500 kcal). The females were randomly subdivided to 2 equal groups (A and B) by using closed envelop. No symptoms were seen in any of the females during the treatment programs.

Eligibility:

55 females were assessed for eligibility in the present study, 5 females were who not agree to the treatment program were excluded from our study, and so 50 females were randomized to the study, and finally, 50 females completed the study and their data had been investigated.

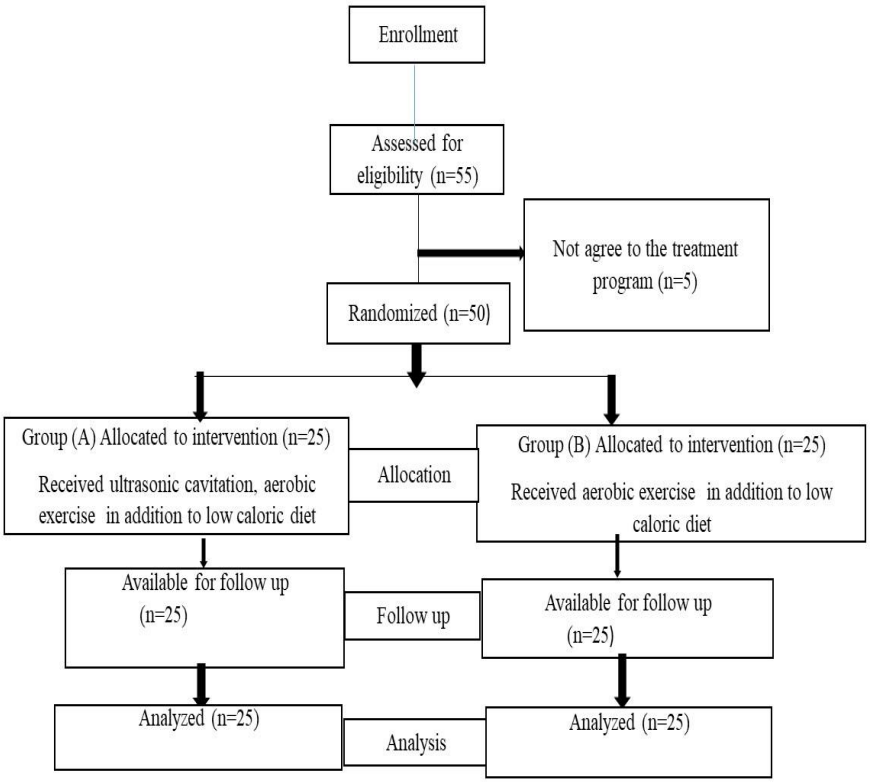

Figure (1): CONSORT Flow chart for patients in the study.

Group (A)

Group (A) composed of 25 females with the mean age and BMI values: 18.92±1.44 years and 30.57±2.13 kg/m^2 respectively. They received ultrasonic cavitation at the abdomen for 30 minutes in addition to moderate aerobic exercise through treadmill using moderate intensity (12–14, according to Borg scale) for 30 minutes and low-caloric diet plan (1500 kcal). Ultrasonic cavitation and treadmill were applied two times per week for 6 weeks.

Group (B)

Group (B) composed of 25 females with the mean age and BMI values: 19.08±1.35 years and 31.01 ±2.36 kg/m^2 respectively. They performed moderate aerobic exercise through treadmill using moderate intensity (12–14, according to Borg scale) for 30 minutes and low-caloric diet plan (1500 kcal). Treadmill was applied two times per week for 6 weeks.

Methods

Before starting treatment program, complete explanation was given to each female about what was going to be performed in the procedure to gain her co-operations and was instructed to evacuate the bladder to be relaxed during the session and to wear comfortable clothes.

Application of ultrasound cavitation:

Before starting the treatment session, every female in group (A) only was instructed briefly and clearly about the mechanism of ultrasound cavitation and its effect in order to gain their confidence and cooperation through the period of this study. The female lied in relaxed supine lying position. The head of cavitation was cleaned by antiseptic solution. The abdomen area was covered with ultrasonic gel, which reached upwards from the diaphragm center to the line extending between two iliac crests downwards and bilaterally from mid-axilla to the iliac crest. The cavitation was applied to the abdomen area with circular and regular movements by the cavitation head. Ultrasound pulsed waves with a frequency of 40 kHz and a power of 45W were delivered through a head with a diameter of 8.0 cm and a power of 45W. It was applied for once daily 30 minutes, it was used twice a week for six weeks Female was advised to drink 1.5 liters of water both before and after each treatment session for the fat elimination process.

Aerobic exercise through treadmill: Every female in both groups (A&B) was instructed to wear light clothes and suitable shoes to be relaxed while training. The female was stand on the cushioned tread and grasp by her both hands the two arms of the treadmill. Treadmill was adjusted to apply moderate intensity training (12–14, according to Borg scale). The Borg scale is a measurement of how hard the body appears to be working based on sign and symptoms such as increased heart rate, increased respiratory rate, increased sweating, and muscle tiredness [16]. This scale ranges from six to twenty, with six represents "no exertion at all" and twenty represents "maximal activity." Practitioners generally agree that a perceived effort rating of 12 to 14 on the Borg Scale indicates that physical activity is being performed at a moderate intensity [17]. It was used for 30 minutes divided into five-minutes warming up, twenty-minutes active exercise and five-minutes cooling down and it was used twice a week for six weeks.

Diet modification: Using low-caloric diet (1500 kcal) consisting of 45% carbohydrates, 35% proteins and 20% fats; for 6 weeks. The diet plan was reviewed weekly to the females in both groups.

Outcome measures

Pre and post treatment program, all females in both groups (A&B) will be evaluated by measuring BMI, waist circumference with tape measurement; waist-hip ratio, percentile body fat and trunk fat with In Body; and abdominal skinfold thickness with caliper.

Standard height scale: was utilized for measuring height of all participated females at both groups before beginning of treatment.

Tape measurement: was utilized for measuring waist circumference of all participated females at both groups pre and post treatment.

Bioelectrical impedance analysis (In Body 230, system h 6 FW_5.53/OS hook): reflects accurate body composition status with the World Highest Direct Segmental Multi-frequency-Bioelectrical Impedance Analysis (DSM-BIA); was utilized for measuring weight, BMI, the waist-hip ratio, percentile body fat and trunk fat for all participated females at both groups pre and post treatment.

Skin-fold caliper: was utilized for measuring the abdominal skin-fold thickness describes the amount of subcutaneous fat when the fold is lifted; it was used for all participated females at both groups pre and post treatment.

Sample size determination

G*POWER statistical programming (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) was used to test size estimation [F tests- MANOVA: Special effects and interaction, α=0.05, β=0.5, number of predictors=2, number of dependents=7, Pillai V = 0.451, and effect size=0.821] and revealed that the appropriate sample size for this study was N=24]. This effect size calculated from pilot study on 20 participants (10 in each group).

Statistical analysis:

SPSS for Windows, version 23 was used for statistical analysis (SPSS, Inc., Chicago, IL). There were 2 independent factors in this study. The first was (tested group); the second was the subject factor, which had 2 levels group A receiving ultrasonic cavitation at abdomen in addition to moderate aerobic exercise and low-

caloric diet plan and group B receiving moderate aerobic exercise and low-caloric diet plan. Second one was (measurement periods), which had 2 levels within the topic factor (pre, post). In addition, 5 dependent factors were investigated in this study. (weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat, trunk fat). Before final analysis, the data were examined for homogeneity of variance, normality and the presence of extreme scores. This investigation was carried out as a prerequisite for the study of difference's parametric calculations. The use of histograms and the normal distribution curve in descriptive analysis revealed that weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat, trunk fat were regularly distributed, and the measured dependent variable did not contradict the parametric assumption. Furthermore, with p values greater than 0.05, testing for covariance homogeneity found no significant differences. Outliers were identified using box and whiskers plots of investigated variable and showed no outliers The Shapiro-Wilk test was performed to determine if the data for weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat, and trunk fat was normally distributed. A 2x2 mixed design MANOVA was used to compare the investigated variables of interest across different testing groups and measuring periods. The initial alpha value was set to 0.05.

III. RESULTS

The participants' general characteristics at both groups (A and B)

Table (1) showed that, at the beginning of the study there was no significant differences between mean values of the age and the height of both groups (A and B).

Table (1) The participants' general characteristics at both groups (A and B)

Items	Group A	Group B	Comparison		S
	Mean ± SD	Mean ± SD	t-value	P-value	
Age (years)	18.92±1.44	19.08±1.35	-0.405	0.687	NS
Height (cm)	162.12±6.84	166.28±8.71	-1.877	0.067	NS

*SD: standard deviation, P: probability, S: significance, NS: non-significant.

Comparison between pretreatment mean values of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of both groups (A and B).

At the beginning of the study, before starting of the treatment program, there was no significant differences between mean weight, body mass index, waist circumference, fat thickness, waist /hip ratio, percentile body fat and trunk fat of the two groups (A and B), as P is equal to 0.174, 0.497, 0.847, 0.74, 0.457, 0.21 and 0.098, respectively, as shown in Table (2).

Table (2) Comparison between the pretreatment mean values of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of both groups (A & B).

	Group A (n=25) Mean± SD	Group B (n=25) Mean± SD	MD	p- value
Weight (Kg)	80.62±10.5	84.96 ±11.44	-4.34	0.174
BMI (Kg/m^2)	30.57±2.13	31.01 ±2.36	-0.44	0.497
Waist circumference (cm)	99.25±9.31	98.68 ±11.19	0.57	0.847
Fat thickness (mm)	27.16±5.45	26.64 ±5.61	0.52	0.74
Waist /hip ratio	0.95±0.04	0.94 ±0.05	0.01	0.457
Percentile body fat (%)	41.1±5.5	43.35 ±6.76	-2.25	0.21
Trunk fat (%)	16.78±3.61	18.6 ±3.93	-1.82	0.098

*Significant level is set at alpha level <0.05, SD: standard deviation, MD: Mean difference, p-value: probability value

Comparison between pre and post-treatment mean difference and percent of improvement of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of group (A) and group (B).

After the end of the treatment program, regarding group (A) (Table 3), after the end of application ultrasonic cavitation on abdominal region as well as aerobic exercises and low caloric diet plan, there was a highly statistically significant decrease in mean values of the weight, body mass index, waist circumference, fat

thickness, waist /hip ratio, percentile body fat and trunk fat after treatment compared with before treatment (p = 0.0001) and percent of improvement was 7.18%, 7.37%, 12.46%, 38.18%, 12.63%, 11.92% and 18.83% respectively.

Regarding group (B) (Table 3), after the aerobic exercise in addition to low caloric diet, there was a statistically significant decrease in mean values of the weight, body mass index, waist circumference, fat thickness, waist /hip ratio, percentile body fat and trunk fat after treatment compared with before treatment (p = 0.0001) and percent of improvement was 4.21 %, 4.35%, 5.36%, 14.71%, 5.31%, 8.21% and 5.43% respectively.

Table 3: Comparison between pre-treatment and post-treatment mean difference and percent of improvement of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of both groups (A & B).

	Group (A)			Group (B)		
	MD	% of change	p- value	MD	% of change	p- value
Weight (Kg)	5.79	7.18 ↓	0.0001*	3.58	4.21 ↓	0.0001*
BMI (Kg/m^2)	2.25	7.37 ↓	0.0001*	1.35	4.35 ↓	0.0001*
Waist circumference (cm)	12.37	12.46 ↓	0.0001*	5.29	5.36 ↓	0.0001*
Fat thickness (mm)	10.37	38.18 ↓	0.0001*	3.92	14.71 ↓	0.0001*
Waist/ hip ratio	0.12	12.63 ↓	0.0001*	0.05	5.31 ↓	0.0001*
Percentile body fat (%)	4.9	11.92 ↓	0.0001*	3.56	8.21 ↓	0.0001*
Trunk fat (%)	3.16	18.83 ↓	0.0001*	1.01	5.43 ↓	0.0001*

*Significant level is set at alpha level <0.05, MD: Mean difference, p-value: probability value

Comparison between the post-treatment mean values of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of both groups (A and B).

On comparison group (A) and group (B), there was a significant decrease at the mean values of both groups post treatment and this significant decrease in favor to group A; weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat (p= 0.035), (p= 0.038), (p= 0.025), (p= 0.0001), (p= 0.0001), (p= 0.045) and (p= 0.0001) respectively, as the mean difference between both groups was -6.55 kg, -1.34 kg/m^2, -6.51 cm, -5.93 mm, -0.06, -3.59 % and -3.97 % respectively, as shown in Table 4.

Table 4 Comparison between post-treatment mean values of the weight, BMI, waist circumference, fat thickness, waist-hip ratio, percentile body fat and trunk fat of *group (A) and group (B).*

	Group A (n=25) Mean± SD	Group B (n=25) Mean± SD	MD	p- value
Weight (Kg)	74.83 ±10.14	81.38±10.93	-6.55	0.035*
BMI (Kg/m^2)	28.32 ±2.16	29.66±2.2	-1.34	0.038*
Waist circumference (cm)	86.88 ±8.29	93.39±11.06	-6.51	0.025*
Fat thickness (mm)	16.79 ±4.11	22.72±5.27	-5.93	0.0001*
Waist/ hip ratio	0.83 ±0.03	0.89±0.05	-0.06	0.0001*
Percentile body fat (%)	36.2 ±5.37	39.79±6.7	-3.59	0.045*
Trunk fat (%)	13.62 ±3.53	17.59±3.88	-3.97	0.0001*

*Significant level is set at alpha level <0.05, SD: standard deviation, MD: Mean difference, p-value: probability value

IV. DISCUSSION

According to statistical analysis of study's results, ultrasonic cavitation in combination with aerobic exercises and a low-calorie diet in group (A) has a positive effect on abdominal obesity and results in a statistically highly significant decrease at mean values of the weight, body mass index, waist circumference, fat thickness, waist /hip ratio, percentile body fat and trunk fat after treatment when compared to the values before treatment (p=0.0001). This obtained results of the study are agreed with those reported by Maha et al. [18] who carried out a study on the use of ultrasound cavitation locally on obese females of aged 30-50 years with a BMI 25-35 kg/m2 and obesity of buttock (waist hip ratio < 0.8) were included; for 12 sessions (15 minute/session) along 6 weeks that found a significant decrease in thickness of fat among females of intervention group after treatment and program