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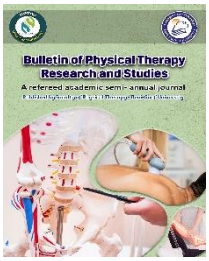

Effect of Cryolipolysis Versus Cavitation Device With Vegan Diet on Serum Lipid Profile in Women With Central Obesity

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RUNNING TITLE: **EFFECT OF CRYOLIPOLYSIS DEVICE VERSUS CAVITATION DEVICE WITH VEGAN DIET ON SERUM LIPID PROFILE IN WOMEN WITH CENTRAL OBESITY**

Abstract

Objectives: This study was designed to examine the difference among cryolipolysis accompanied with vegan diet against cavitation device accompanied with vegan diet on serum lipid profile in women having central obesity.

Methods: Sixty volunteers' adult females had been involved in this study, aged from 25 to 40 years old. They were given their treatment program from July 2023 to October 2023, a written consent was obtained from each patient. The patients were randomly assigned to one of three equivalent groups; Group A received Cryolipolysis device with vegan diet, Group B received Cavitation device with vegan diet, while Group C received vegan diet only. Body weight, BMI, waist circumference, abdominal skin fold caliper, and serum lipid profiles were monitored for three months during the study.

Results: The results indicated that women in Groups A, B, and C did not differ significantly (P>0.05) in terms of age, weight, height, or body mass index. There were significantly (P<0.05) decreased in weight, BMI, waist circumference, skin fold caliper in abdomen region, and serum lipid profiles after treatment in comparison with before treatment within Group A followed by Group B and then Group C. The women with central obesity in Group B improved body measurement and serum lipid profiles compared to Group A and Group C. No significant differences (P>0.05) in weight, BMI, waist circumference, skin fold calliper in abdominal region, and serum lipid profiles at pre-treatment among Groups A, B, along with C. However, a significant difference (P<0.05) was found in weight, BMI, waist circumference, skin fold calliper in abdominal region, and serum lipid profiles at after treatment among groups A, B, and C.

Conclusion: It was concluded that the cavitation technique with vegan diet had the most noticeable decline in measured variables and noticeable improvement in the shape conturing of abdomin followed by cyolipolysis technique with vegan diet then receiving vegan diet only.

Keywords: Central obesity, Serum lipid profile, Cryolipolysis, Cavitation and Vegan diet.

Introduction

Women who are obese run the risk of acquiring physical and mental health problems. It has been demonstrated that obesity increases the risk of developing several cancers, including endometrial, breast, gallbladder, oesophageal, in addition to renal cancers. Obesity has a detrimental effect on both fertility and contraception in terms of reproductive health. Furthermore, obesity has been linked to increased risks of congenital abnormalities, early miscarriages, cesarean sections, high-risk obstetric disorders, and maternal and newborn mortality [1].

It makes sense that a vegan diet, which excludes all animal products, would help reduce the chance of developing atherosclerosis because animal products are the main source of cholesterol and saturated fats. In fact, a well-balanced vegan diet may actually lower the risk of cardiovascular disease, according to some research. Due to its low content of saturated fats and high content of plant-based foods like nuts, fiber, vegetable oils, and vegetable proteins, which lower serum cholesterol and may improve endothelial functioning, a vegan diet may be health beneficial [2].

A higher concentration of phytosterols—plant-derived compounds that are similar to cholesterol but can lower lipid levels—might also be especially important. Total cholesterol (TC) and low-density lipoprotein (LDL) cholesterol concentrations may decrease as a result of phytosterols' effects on lipoprotein metabolism and reduction of cholesterol absorption in the digestive system (LDL-C) [3].

But there is still uncertainty about how a vegan diet affects other lipid-related metrics. For example, it is unclear how a vegan diet affects the amount and caliber of high-density lipoproteins (HDL). Together with its primary apolipoprotein, apolipoprotein AI (apoAI), HDL particles have an atheroprotective effect are involved in the process of transporting excessive cholesterol from peripheral tissues towards the liver, a process known as reverse cholesterol transport, and they are crucial for this process. Moreover, thrombosis, vascular inflammation, and LDL oxidation are inhibited by HDL particles. It is noteworthy that different HDL particles may not have the same level of protection due to their heterogeneous composition [3].

As a result, the anti-atherogenic potential of HDL particles cannot be accurately determined by the concentration of HDL cholesterol (HDL-C). This means that more research is required to fully understand the characteristics of HDL particles, including the percentage of the HDL fraction that is both apoAI-containing and apoAII-free (LpAI), also known as pre-b1-HDL, an HDL precursor.Evaluation of HDL constituents other than cholesterol lipids, such as phospholipids, appears to be equally significant. Moreover, even though a vegan diet contains plant-based antioxidants, it has been proposed that low vitamin B12 intake and elevated homocysteine levels could raise the risk of oxidative stress. Thus, there may be a greater likelihood of atherosclerosis and oxidative lipid alteration [4].

Globally, body shaping is an essential medical aesthetic requirement. The desire of people to have a more appealing body type has prompted the development of cutting-edge, secure, comfortable, non-invasive, and downtime-reducing procedures. Because non-invasive therapies gradually remove fat, improve texture, and contour the body, most patients prefer them to invasive procedures and surgery [5].

Localized adiposity, an essentially unattractive disorder, is the abnormal collection of fat in normally anatomical locations. Although liposuction has long been the go-to operation for body sculpting, other options have emerged in response to the procedure's possible negative effects. To destroy adipocytes, a number of therapies, such as mesotherapy, radiofrequency, and ultrasound, have been developed. Different mechanisms are used by each technique to induce necrosis or apoptosis in the targeted adipocytes. Cryolipolysis, which involves cold-induced panniculitis, is a novel noninvasive method for reducing localized fat. The idea behind this technique is that tissues rich in lipids are more vulnerable to damage from cold than the surrounding tissues rich in water [5].

One of the main distinctions between ultrasound cavitation and liposuction is the lack of surgical adverse effects. Indeed, the non-invasive method of delivering energy to fat would reduce the risks associated with periprocedural morbidity, such as infection, scarring, and anesthesia. There aren't many research comparing ultrasound cavitation and cryolipolysis for patients with localized abdominal obesity, as far as we are aware. Although liposuction is a successful technique, more secure methods are still needed for fat reduction. Instead of undergoing dangerous operations or surgery, most people stick to safe techniques that enhance body sculpting and progressively reduce body fat. Cavitation is a new ultrasound procedure that removes the need for surgery [6].

Methods

Subjects

Sixty women participated in this study to examine the impact of cryolipolysis versus cavitation device with vegan diet. They selected randomly into three groups from Out Patient Clinic of El-Safa and El-Marwa poly clinics in Assuit.

Ethical consideration

The researchers contacted the patients and asked whether they would be interested in participating in the study. Information regarding (risks/benefits, voluntary involvement, and procedures) was thoroughly presented by the study's researcher. We made sure patients had plenty of time to think about it, ask questions, and provide their informed, voluntary consent. Strict adherence to the patient's rights as well as confidentiality was maintained.

Ethical approval

The study was approved by the Faculty of Physical Therapy at Cairo University before it began with the number (P.T.REC/012/004629). There was a total of sixty females divided equally among three groups. As following:

- Group A received cryolipolysis in addition to vegan diet,
- Group B received cavitation in addition to vegan diet and
- Group C received vegan diet alone.

Randomization

Twenty individuals from each of Group's A, B, and C were randomized into each group by a blinded research assistant using sealed envelopes containing numbers generated by a random number generator. So that groups A, B, and C would all receive an equal number of participants, the randomization was limited to permuted blocks. For each group, individuals received an envelope with their allocated sequence. All patients who met the inclusion as well as exclusion criteria were told about the study's purpose and procedures.

Criteria for the patient selection:

Inclusion criteria

- They were between 25 and 40 years old.
- Their BMIs varied from 35 to 39.9 kg/m2.
- all participants exhibited central obesity, defined as a waist circumference greater than 102 cm (40 in).
- For all women, the mean number of prior deliveries is approximately four.
- The women all led almost sedentary lives.
- Serum lipid profiles taken while fasting were within the borderline as well as high risk ranges.

Exclusion criteria

- The onset of epilepsy.
- Cardiac disease and utilizing a pacemaker.
- smoking a lot.
- • A disease affecting the kidneys, liver, or endocrine system.
- • pathology of the lungs or the respiratory system.
- * Women who are anticipating a child.

- • Individuals who are taking any kind of medication, including those for lipid-lowering, vitamin, or antioxidant purposes.
- • Medications for fighting obesity
- Skin Allergy
- IUD as contraceptive method

Material

A. Evaluative equipment

1. Anthropometric Measurements ((a)Weight,(b) BMI,(c) waist circumference)
2. Pre and post-test skin fold calliper in abdominal region.
3. Pre and post-test serum lipid profile.
4. Pre and post-test blood pressure measurement by sphygmomanometer

B. Training Equipment

- 1. Cryolipolysis: The AF2000-02 model, which is manufactured in China and is used for all cases in group A, utilizes a vacuum-based big applicator called Cool Max as well as vacuum medium applicators called CoolCore or Cool-Curveþ for the belly. Each session lasts thirty minutes and is repeated every two weeks for three consecutive three-month periods.
- 2. Cavitation: the whole B group was subjected to a 45 KHz frequency for 30 minutes two times per week for 3 consecutive months using a Cavitation Device (Item No.: AU61, manufactured in China).

Evaluative procedures

1. Carefully recorded patient's medical history to gather information about her overall health.

2. Before and throughout the application, the patient's vital signs were monitored, including blood pressure, temperature, respiration rate, as well as heart rate.

Anthropometric Measurements

- Anthropometric measures were taken from each subject at before treatment and again 90 days following treatment. The subjects did not wear shoes when their height and weight were measured. An elastic was used to measure the abdomen's circumference.
- It is important to note that every point of measurement was documented at the baseline to guarantee that future measurements would be taken from the same area.

- The measurement of the waist circumference using a tape measure will be conducted at various anatomical locations, including the umbilicus, just under the ribs, right over the crest of the iliac, and halfway among the lower rib as well as the iliac crest. It is advised by the NHLBI practical guide to measure slightly above the iliac crest, When the subject exhales and stands with both feet touching and their palms placed freely, the waist circumference measurement is obtained [5]
- The tape measurement was adjusted until it is perpendicular to the longitudinal axis of the body and parallel to the ground; nevertheless, it doesnt apply stress to the abdominal wall. [5]
- skinfold Caliper. Patients who can be measured at both the before treatment and 90 days post-treatment had their skinfold thickness measured using a skinfold caliper (RMC, Amparo, SP, Brazil).
- To assess the lipid profiles, blood samples were taken both pre and post-treatment. Following 12 to 14 hours of fasting at night, blood samples was drawn from all participants using a venipuncture in the morning. Laboratory processing and analysis of the samples followed straight away after collection.
- • The following components' serum lipid values was collected: cholesterol, triglycerides, in addition to LDL. This analysis didn’t include subjects whose baseline laboratory values are outside of the reference range.

Treatment Protocol

- 1. For group A, cryolipolysis is performed using a vacuum-based large applicator (Cool Max) as well as vacuum medium applicators (whether it's CoolCore or Cool-Curve) upon the abdomen for thirty minutes, every two weeks for 3 consecutive months. The device is manufactured in China and is part of the optimized cryolipolysis 360 devices. Cryolipolysis was utilized for treating the subcutaneous-fat layer in various abdominal locations. For thirty minutes, the cryolipolysis devices reduced its temperature to (−8∘ C)

- According to the size of the targeted fat area and the anatomical restrictions of the applicator placement, areas were be treated using either the medium or large applicator.

- Patients were comfortably positioned in either the side-lying or supine position, using a 45∘ stretcher inclination, during the therapy sessions. Initiation of vacuum suction was done after positioning the curved vacuum applicator within the center of the area to be treated region. While the applicator works, the vacuum was positioned over the treatment region and supported by pillows.
- It uses a transducer with a width of 45 mm as well as a power of 3 watts/cm2 to give out low-frequency ultrasonic pulsed waves at 45kHz. The patient lied comfortably on supine while the transducer was put on an area of their abdomen that has been coated using conduction gel. A 30-minute treatment was conducted two times per week for 3 months to treat the abdomen area.

Diet intervention

A well-balanced vegan diet (sometimes called a lacto-ovo vegetarian diet) included dairy and eggs but prohibited meat, fish, and fowl.Vegan diet: each day's allotment was determined by consuming 2,000 calories. [8] Low intakes of saturated fat (≤5% of energy) and free sugars (<5% of energy), moderate intakes of protein (<15% of energy), high intakes of fiber (≥45–60 g/day) , salt (1500 mg/day), and total fat (10–20% of energy) are the characteristics that should define it. Vitamin D (a food-fortified vitamin) and vitamin B12 from reputable sources must be included in the necessary supplementation [1]

Statistical Analysis

Both the homogeneity of variance and the normality assumption tests have been performed on the data. The data was found to follow a normal distribution (P>0.05) following the elimination of outliers identified by box and whiskers plots, according to a normality test of data utilizing the Shapiro-Wilk test. Furthermore, no significant difference (P>0.05) was found when Levene's test for homogeneity of variance was applied. These results made it possible to perform both parametric and non-parametric analyses. Parametric analysis is performed on data that follows a normal distribution.

Version 25 of the statistical SPSS Package program for Windows was used to conduct the statistical analysis (SPSS, Inc., Chicago, IL). For age, weight, height, BMI, waist circumference, skin fold caliper, total cholesterol, triglycerides, HDL, and LDL variables, the data are presented as mean and standard

deviation. Clinical general characteristics factors were compared between three groups using one-way analysis of variance (ANOVA-test). Using a mixed design 3 x 2 MANOVA-test, the main dependent variables (weight, height, BMI, waist circumference, skin fold caliper, total cholesterol, triglycerides, HDL, and LDL) were measured during two levels (pre- and post-treatment). The 1st independent variable (between subject factors) was the tested group with three levels (group A, B, and C). When the MANOVA test found a significant P-value for one of the major dependent variables, we utilized the Bonferroni adjustment test to compare the corresponding pairs of groups inside and between them. At the probability level ($P < 0.05$), all statistical analyses were found to be significant.

Results

In the present study, an overall of 60 women with central obesity took-part in this study and randomized into 3 groups (20 women /group). Table 1 shows that there are no significant differences ($P<0.05$) in the following variables: age (P=0.274), weight (P=0.373), height (P=0.643), and BMI (P=0.755) across the groups of women with central obesity.

Table 1. Patient clinical general characteristics between groups

Variable	Groups			*P*-value
	Group A (n=20)	Group B (n=20)	Group C (n=20)	
Age (year)	35.13 ±4.61	31.90 ±6.36	33.43 ±3.91	0.274
Weight (kg)	102.64 ±8.56	99.00 ±6.77	98.94 ±7.74	0.373
Height (cm)	163.00 ±7.82	161.70 ±4.37	160.92 ±4.35	0.643
BMI (Kg/cm^2)	38.72 ±1.76	38.11 ±2.12	38.44 ±2.23	0.755

Data are reported as mean ±standard deviation (SD) and compared statistically by ANOVA test.
P-value: probability value P-value>0.05: non-significant

Statistical analysis for body measurements (weight, BMI, waist circumference, and skin fold caliper) within every group (Table 2) revealed that a significant ($P<0.05$) decline at post-treatment compared to pre-treatment within Group A, Group B, and Group C in weight (P=0.016, P=0.0001, and P=0.008, respectively), BMI (P=0.0001, P=0.0001, and P=0.001, respectively), waist circumference (P=0.006, P=0.0001, and P=0.011, respectively), and skin fold caliper (P=0.0001, P=0.0001, and P=0.0001, respectively). Moreover, the women with central obesity in Group B who received the cavitation with vegan diet improved weight, BMI, waist circumference, and skin fold caliper decreasing (15.67,15.58,

15.40, and 31.88 %, respectively) followed by women in Group A who received the cryolipolysis with vegan diet (10.79, 11.50, 8.71, and 17.22%, respectively), and then those in Group C who received diet only (10.11, 9.20, 6.95, and 12.44%, respectively).

Statistical analysis for body measurements (weight, BMI, waist circumference, and skin fold caliper) among Groups A, B, and C (Table 2) revealed that no significant differences ($P>0.05$) before treatment in weight ($P=0.934$), BMI ($P=0.968$), waist circumference ($P=0.925$), as well as skin fold caliper ($P=0.368$). Nevertheless, a significant difference ($P<0.05$) was observed between Group A, Group B, and Group C following treatment in terms of weight ($P=0.036$), BMI ($P=0.018$), waist circumference ($P=0.003$), in addition to skin fold caliper ($P=0.0001$). Moreover, these significant decreases in mean values of weight, BMI, waist circumference, and skin fold caliper after treatment favoring of Group B, followed by Group A, and then Group C.

The results of the post-hoc test (Table 2) showed that there were statistically significant differences ($P<0.05$) in weight, BMI), waist circumference, as well as skin fold caliper following treatment when comparing Group A with Group B ($P=0.001$, $P=0.037$, $P=0.027$, and $P=0.0001$, respectively) and Group B with Group C ($P=0.0001$, $P=0.026$, $P=0.0001$, and $P=0.0001$, respectively). However, when comparing Group A with Group C, no significant differences were found ($P>0.05$). The post-hoc test as well as mean differences among pairwise of groups revealed that the cavitation with vegan diet program (Group B) gave the best values of decreasing weight, BMI, waist circumference, and skin fold caliper.

Table 2: Within and between group comparison for body measurements

Variables	Items	Groups (Mean ±SD)			*P*-value	Post-hoc (*P*-value)		
		Group A (n=20)	Group B (n=20)	Group C (n=20)		Group A *vs.* Group B	Group A *vs.* Group C	Group B *vs.* Group C
Weight	Pre-treatment	97.61 ±8.02	99.00 ±6.77	98.60 ±7.95	0.934	1.000	1.000	1.000
	Post-treatment	87.08 ±7.97	83.49 ±6.90	88.63 ±5.61	0.036*	0.001*	0.985	0.0001*
	Change (MD)	10.53	15.51	9.96				
	Improvement %	10.79%	15.67%	10.11%				
	95% CI	2.04 – 19.02	8.93 – 22.08	2.70 – 17.22				
	P-value	0.016*	0.0001*	0.008*				
BMI	Pre-treatment	38.36 ±1.77	38.11 ±2.12	38.15 ±2.15	0.968	1.000	1.000	1.000
	Post-treatment	33.95 ±1.88	31.79 ±2.06	34.64 ±1.59	0.018*	0.037*	1.000	0.026*
	Change (MD)	4.41	6.32	3.51				
	Improvement %	11.50%	16.58%	9.20%				
	95% CI	2.08 – 6.74	4.51 – 8.12	1.51 – 5.50				
	P-value	0.0001*	0.0001*	0.001*				
Waist circumference	Pre-treatment	111.08 ±5.10	110.10 ±4.20	110.96 ±6.25	0.925	1.000	1.000	1.000
	Post-treatment	101.41 ±4.86	93.15 ±6.28	103.25 ±7.88	0.003*	0.027*	1.000	0.0001*
	Change (MD)	9.67	16.95	7.71				
	Improvement %	8.71%	15.40%	6.95%				
	95% CI	2.85 – 16.47	11.67 – 22.22	1.88 – 13.53				
	P-value	0.006*	0.0001*	0.011*				
skin fold calliper	Pre-treatment	35.31 ±0.94	34.32 ±1.43	35.12 ±1.44	0.368	0.677	1.000	0.692
	Post-treatment	29.23 ±1.10	23.38 ±2.15	30.75 ±1.73	0.0001*	0.0001*	0.304	0.0001*
	Change (MD)	6.08	10.94	4.37				
	Improvement %	17.22%	31.88%	12.44%				
	95% CI	4.25 – 7.91	9.52 – 12.35	2.81 – 5.93				
	P-value	0.0001*	0.0001*	0.0001*				

Data are expressed as mean ± standard deviation (SD) MD: Mean difference 95% CI: confidence interval P-value: probability value * Significant (P<0.05)

Statistical analysis for serum lipid profile measurements (triglycerides, total cholesterol, HDL, and LDL) within each group as shown in (Table 3) indicated that there was significant (P<0.05) decline after treatment compared to before treatment within Group A, Group B, as well as Group C in triglycerides (P=0.008, P=0.0001, and P=0.023, respectively) and total cholesterol (P=0.001, P=0.0001, and P=0.007, respectively). In Group A, Group B, and Group C, there was a significant rise in HDL levels after treatment compared to before treatment (P<0.05), with corresponding p-values of 0.023, 0.0001, and 0.037. Both Group A (P=0.0001) and Group B (P=0.0001) showed a significant reduction in LDL levels

after treatment compared to before (P=0.0001), but no significant difference (P>0.05) in LDL within Group C (P=0.132). Moreover, the women with central obesity in Group B who received the cavitation with vegan diet improved triglycerides, total cholesterol, HDL, and LDL (40.50, 33.39, 28.80, and 28.36%, respectively) followed by women in Group A who received the cryolipolysis with vegan diet (19.86, 25.04, 20.69, and 25.93%, respectively), and then those in Group C who received diet only (14.90, 18.00, 9.46, and 7.78%, respectively).

Statistical analysis for serum lipid profile measurements (triglycerides, TC, HDL, and LDL) between groups A, B, and C (Table 3) revealed that significant differences has been detected (P>0.05) before treatment in triglycerides (P=0.152), TC (P=0.579), HDL (P=0.547), and LDL (P=0.601). while, a significant differences was detected (P<0.05) among Group A, Group B, and Group C after treatment in triglycerides (P=0.009), TC (P=0.020), HDL (P=0.029), and LDL (P=0.0001). Moreover, these significant differences in mean values of triglycerides, TC, HDL, and LDL after treatment favoring Group B, followed by Group A, and then Group C.

Post-hoc test (Table 3) showed that there were significant differences (P<0.05) in triglycerides, TC, and HDL after treatment between pairwise of Group A versus Group B (P=0.009, P=0.038, and P=0.046, respectively) and Group B versus Group C (P=0.018, P=0.026, and P=0.013, respectively), but no differences (P>0.05) between pairwise of Group A versus Group C (P=1.000, P=0.993, and P=1.000, respectively). Table 3 displays the results of the post-hoc test for LDL After treatment, which revealed statistically significant differences when comparing Group A with Group C (P=0.005) and Group B with Group C (P=0.0001), however no such difference when comparing Group A with Group B (P=1.000) (P>0.05). The post-hoc test as well as mean differences between pairwise of groups revealed that the cavitation with vegan diet program (Group B) gave the best values of triglycerides, TC, HDL, and LDL.

Table 3: Within and between group comparison for serum lipid profile measurements

Variables	Items	Groups (Mean ±SD)			*P*-value	Post-hoc (*P*-value)		
		Group A (n=20)	Group B (n=20)	Group C (n=20)		Group A *vs.* Group B	Group A *vs.* Group C	Group B *vs.* Group C
Triglycerides	Pre-treatment	172.83 ±19.06	186.15 ±34.79	168.23 ±12.94	0.152	0.728	1.000	0.171
	Post-treatment	138.50 ±17.63	110.76 ±15.89	143.16 ±23.67	0.009*	0.035*	1.000	0.018*
	Change (MD)	34.33	75.39	25.07				
	Improvement %	19.86%	40.50%	14.90%				
	95% CI	4.33 – 64.33	55.76 – 95.01	8.08 – 42.06				
	P-value	0.008*	0.0001*	0.023*				
Total cholesterol	Pre-treatment	225.66 ±17.68	211.23 ±17.05	220.32 ±23.12	0.579	0.980	1.000	1.000
	Post-treatment	169.16 ±39.67	140.70 ±40.93	180.66 ±20.99	0.020*	0.038*	0.993	0.026*
	Change (MD)	56.50	70.53	39.66				
	Improvement %	25.04%	33.39%	18.00%				
	95% CI	23.72 – 89.27	45.14 – 95.92	11.63 – 67.67				
	P-value	0.001*	0.0001*	0.007*				
HDL	Pre-treatment	34.66 ±3.61	35.00 ±4.02	36.69 ±6.12	0.547	1.000	1.000	1.000
	Post-treatment	41.83 ±2.92	45.08 ±3.49	40.16 ±3.81	0.029*	0.046*	1.000	0.013*
	Change (MD)	7.17	10.08	3.47				
	Improvement %	20.69%	28.80%	9.46%				
	95% CI	0.33 – 10.66	6.08 – 14.08	0.72 – 9.55				
	P-value	0.023*	0.0001*	0.037*				
LDL	Pre-treatment	142.67 ±17.51	142.80 ±12.87	145.85 ±12.23	0.601	1.000	0.985	0.995
	Post-treatment	105.67 ±13.12	102.30 ±14.13	134.50 ±23.01	0.0001*	1.000	0.005*	0.0001*
	Change (MD)	37.00	40.50	11.34				
	Improvement %	25.93%	28.36%	7.78%				
	95% CI	27.55 – 46.45	26.98 – 54.01	3.56 – 26.25				
	P-value	0.0001*	0.0001*	0.132				

Data are expressed as mean ± standard deviation (SD) MD: Mean difference 95% CI: confidence interval P-value: probability value * Significant (P<0.05)

Discussion

This study was designed to compare between the effect of cryolipolysis with vegan diet, cavitation device with vegan diet and vegan diet only in females with central obesity.

This study was conducted on 60 females were randomized into three groups group (A) (n=20), group (B) (n=20) as well as group (c) (n=20) who were selected randomly from Elsafa and Elmarwa poly clinics in Assuit, Egypt, matched for measured variables They accepted to take part in the research; their

ages varied from twenty-five to forty. They were received their treatment program from July 2023 to October 2023, A written consent was obtained from each patient. Group (A) received Cryolipolysis device in addition to vegan diet, group (B) received Cavitation device in addition to vegan diet while group (C) received vegan diet alone. In our study, we evaluated (Body weight, BMI, waist circumference, abdominal skin fold calliper and serum lipid profile) for three months. The study result revealed that the females in group B showed the most noticeable decline in measured variables and noticeable improvement in the shape contouring of abdomen followed by group A then group C.

Findings of this study indicated that: no significant differences was found ($P>0.05$) in mean values of women age ($P=0.274$), weight ($P=0.373$), height ($P=0.643$), and BMI ($P=0.755$) among Group A, Group B, and Group C. There was significantly ($P<0.05$) decreased in weight BMI waist circumference skin fold caliper in abdomen region and serum lipid profile after treatment in comparison with before treatment within Group A ($P=0.0001$) followed by Group B ($P=0.0001$) then Group C ($P=0.0001$). The women with central obesity in Group B improved weight decreasing (15.67%) followed by women in Group A (10.79%), and then those in Group C (10.11%). No significant difference ($P>0.05$) in the mean ±SD values of weight ($P=0.934$) at pre-treatment among Groups A, B, and C. However, there was significant difference ($P<0.05$) in the mean ±SD values of weight ($P=0.036$) after treatment between groups A, B, and C.

The following studies supported our findings:

The study [5] examined how cavitation, radiofrequency, as well as cryolipolysis affected subcutaneous fat in centrally obese teens. It found that following two months of treatment, no statistically significant differences was found in BMI, weight, or visceral adipose tissue (VAT) among the groups. On the other hand, the suprailiac skin fold, waist-hip ratio, SAT, as well as hunger level were significantly different among the three groups ($P=0.001$). The Cavitation along with radiofrequency group (A) demonstrated higher decline compared to the Cryolipolysis group (B), and the Cryolipolysis group was more effective than diet group (C).

A study comparing the impact of two treatments on leptin regulation within centrally obese patients found no statistically significant differences in insulin as well as leptin levels following

3 months of intervention among cavitation plus radiofrequency and cryolipolysis [9]. But the cavitation group had statistically significant improvements in waist circumference, skinfold, weight reduction, as well as ($P<0.05$). In addition, the research groups showed statistically significant differences ($P<0.05$) from the diet only in each outcome measure when compared to cryolipolysis and cavitation-radiofrequency. Furthermore, other from the diet group's leptin level ($P=0.14$), all outcome variables showed statistically significant variations between the pre-treatment and post treatment results in every group ($P<0.05$).

After two months, each of the three groups revealed statistically significant enhancements in all evaluated variables, according to the study of [7], which compared ultrasound cavitation with cryolipolysis for non-invasive body contouring. After therapy, neither the bodyweight nor the BMI differed significantly across the groups. Waist and suprailiac skinfold measurements improved more in the groups that had cryolipolysis as well as ultrasound cavitation compared to the diet-only group after treatment. After treatment, neither the cavitation group nor the cryolipolysis group showed any statistically significant differences in waist circumference nor suprailiac skinfold.

The following studies came in disagreement with us like:
To compare Ultrasound Cavitation with Cryolipolysis for Patients with Central Obesity, researchers carried out the study described in [10]. Ten (10) male and fifteen (15) female patients served as subjects. Both Group A (by employing cavitation) and Group B (by employing cryolypolysis) showed a statistically significant decrease in central obesity, as measured by BMI, abdomen fat%, and WC. However, neither group showed a statistically significant decrease in central obesity defined as BMI, WC, or both. Results were better in Group B compared to Group A. Group A showed a 2.94% enhancement in BMI, an 11.07% reduction in abdominal fat%, and a 5.59% enhancement in WC. Group B showed a 3.62% reduction in BMI, a 19.11% decline in abdominal fat%, and a 4.68% enhancement in WC. The cause of disagreement is the sample size was very small and both Genders also included.

The purpose of the pilot interventional trial described in [11] was to assess the efficacy of a non-invasive selective technique for abdominal fat removal using ultrasound cavitation in conjunction with cryolipolysis.

It showed that out of a total of 90 females, ranging in age from 18 to 65, 30 were randomly assigned to one of three groups. During the course of 8 weeks, subjects in Group 1, the control group, received a diet alone; subjects in Group 2, cryolipolysis and diet, and subjects in Group 3, a mix of ultrasonic cavitation, cryolipolysis, and diet, were treated. At the beginning, middle, and end of the experiment, researchers examined anthropometric variables such as total body weight, body fat mass, fat-free mass, as well as abdominal circumference.

Based on the findings, at the end of the intervention, each of the three groups demonstrated statistically significant reductions in every measure ($P<0.01$). The combined therapy considerably reduced weight, body fat mass, BMI, as well as abdomen circumference compared to the control group ($P<0.01$), except for fat-free mass ($P= 0.66$). The groups receiving cryolipolysis alone and combined therapy did not differ significantly from one another. There is debate because of a very limited time frame—just two months.

Conclusion

It was concluded from this study that the cavitation technique with vegan diet had the most noticeable decline in measured variables and noticeable improvement in the shape contouring of abdomen followed by cryolipolysis technique with vegan diet then receiving vegan diet only.

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