

Effect of Cryolipolysis Versus Ultrasound Cavitation on Post-Menopausal Abdominal Adiposity

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ABSTRACT

Background: For spot reduction of adipose tissue, cryolipolysis and ultrasound cavitation are quickly emerging as the most often used substitutes for liposuction. These methods are also emerging as prominent noninvasive therapies because of their simplicity of use and few side effects. **Purpose:** This study aimed to assess the effects of cryolipolysis and ultrasonic cavitation on post-menopausal abdominal adiposity. **Subjects and methods:** This research, which included sixty postmenopausal women, compared the effects of cryolipolysis and ultrasonic cavitation on postmenopausal abdominal (Adiposity). They were chosen at random from the Outpatient Clinic of Om El Masryeen General Hospital in Giza. Their ages varied from 50 to 60 years. Their body mass index (BMI) was above 30 kg/m². All of the women were at least two years post-menopausal. All women suffered from abdominal adiposity if their waist circumference (WC) is greater than 90 cm and their waist-hip ratio is greater than 0.85.

Results: Age, weight, height, and BMI did not significantly differ between groups A and B, according to the study's findings ($p > 0.05$). Following treatment, both groups A and B showed a substantial decrease in subcutaneous fat thickness (SFT), WC, hip circumference, waist-to-hip ratio (WHR), and BMI. BMI, WC, hip circumference, WHR, and SFT did not significantly differ between groups A and B either before or after treatment.

Conclusion: It may be determined that both cryolipolysis and ultrasonic cavitation had the same impact on lowering postmenopausal abdominal adiposity by decreasing BMI, WC, hip circumference, WHR, and SFT.

Keywords: Cryolipolysis, Ultrasound cavitation, Low caloric diet, Abdominal adiposity.

INTRODUCTION

Women in their midlife frequently complain from weight gain, especially during the menopausal transition. Second, women have a larger distribution of central body fat, as evidenced by comparatively higher subcutaneous adipose tissue before the first menstrual period (FMP) compared to comparatively greater subcutaneous adipose tissue deposition following the FMP ⁽¹⁾. Menopausal estrogen withdrawal impairs metabolism and causes a shift in the distribution of body fat from a gynoid to an android pattern ⁽²⁾.

Together with a sedentary lifestyle and altered eating habits, the relative excess of androgens at this time increases total and central adiposity puts women at high risk for cardiovascular illnesses ⁽³⁾.

Visceral fat, also known as organ fat or intra-abdominal fat, is located outside the peritoneal cavity, positioned between the body and internal organs, as opposed to subcutaneous fat, which is located beneath the skin, and intramuscular fat, which is distributed throughout skeletal muscle. An excess of visceral fat that results in an excessive protrusion of the abdomen is the hallmark of central adiposity, sometimes known as the "pot belly" or "beer belly" effect ⁽⁴⁾.

A growing number of non-invasive body contouring procedures target specific ultrasonic targets and specifically destroy local subcutaneous adipose tissue, therefore safely and efficiently reducing modestly localized fat deposits in postmenopausal women. Neighboring tissues including muscles, connective tissue, blood arteries, and nerves are not harmed by this technology ⁽⁵⁾.

Cryolipolysis is a non-invasive technique that reduces subcutaneous fat without harming surrounding tissues by selectively destroying fat cells by regulated chilling ⁽⁶⁾. Therefore, the cold triggers an inflammatory reaction and fat cell fibrosis, which results in adipocyte programmed death (apoptosis) and progressively reduces the fat layer. Nonetheless, the results of cryolipolysis might be seen around two months after treatment ⁽⁷⁾.

By targeting certain depths in subcutaneous adipose tissue, focused US can reduce exposure and damage to tissues outside the target zone. The intensity is concentrated on the subcutaneous fat in order to eradicate adipocytes. Typical healing mechanisms that include the slow metabolism of free lipids include lipid desorption and lesion repair ⁽⁸⁾.

So, the aim of this study was to assess the effects of cryolipolysis and ultrasonic cavitation on post-menopausal abdominal adiposity.

SUBJECTS AND METHODS

This research, which included sixty postmenopausal women, compared the effects of cryolipolysis and ultrasonic cavitation on postmenopausal abdominal adiposity. They were chosen at random from the Outpatient Clinic of Om El Masryeen General Hospital in Giza. Their ages varied from 50 to 60 years.

Inclusion criteria: BMI was above 30 kg/m². All of the women were at least two years post-menopausal. All

women suffered from abdominal adiposity if their WC was greater than 90 cm and their waist-hip ratio was greater than 0.85.

Exclusion criteria: Women with malignancies or undergoing radiation, renal or liver illness, circulatory malfunction, fatty liver, post-surgical abdominal scar, metabolic problems and women with an implanted medical device (Such as a pacemaker).

Design of the study: Randomized controlled study (2 groups with pre-test and post-test design).

All women were divided into 2 equal groups:

Group A (Cryolipolysis group): It comprised of thirty postmenopausal women who were treated with a low calorie diet (1200 kcal/day) and cryolipolysis for 60 minutes, once every four weeks for three months.

Group B (Ultrasound cavitation group): It included thirty postmenopausal women who were treated with a low-calorie diet (1200 kcal/day) and ultrasonic cavitation for 40 minutes twice a week for three months.

Outcome measures:

- 1- BMI assessment:** It is a convenient index of relative weight through a ratio using an equation to indicate and characterize body fatness ($BMI = \text{weight (Kg)} / \text{height (m}^2\text{)}$).
- 2- WC, hip circumference and WHR:** Each woman in both groups (A & B) had her waist and hip circumferences measured with tape before and after treatment, and the waist-to-hip ratio was determined.
- 3- Skin fold caliper:** It was utilized to assess the abdominal SFT of each woman in both groups (A & B) before and after treatment.

Treatment procedures:

1- Cryolipolysis: 3 max cold shaping device (model ESM-8100MO) is a Korean-made gadget that can freeze fat without harming the skin. It was used to treat all women in group A for 60 minutes, once every four weeks for three months.

The woman was in a supine posture and totally relaxed after being told to empty her bladder in order to rest throughout the session. There were three major sections of the abdomen: One on the right, one on the left, and one in the middle. To protect the skin, a cold gel pad was placed over the fatty region that would be treated first. The session duration was split evenly between them, meaning that each area got 20 minutes of cryolipolysis.

The area that needed to be treated was then covered with a big applicator that resembled a cup. This cup applicator then applies a suction, which eventually

sucks in the treated roll of fat. During this motion, the woman experienced a strong tugging feeling. During the first 10 minutes, the temperature within the cup was progressively reduced until it reached a predefined value of around -7 or -8 degrees Celsius.

This caused the fat cells inside the roll of fat to gradually freeze. For three months, each woman had one treatment every four weeks, for a total of three sessions. The cup applicator stayed in contact with the treated roll of fat for 20 minutes using a suction method, and each region treated with a single cup applicator needed to cool for 20 minutes (**Figure 1**).

After 20 minutes of cooling in each given area, a gentle massage was applied over the treated area for 10 minutes to help temperature return back to normal. The woman noticed a small burning sensation in the region as the temperature in that location returned to normal.



Figure (1): Cryolipolysis application.

2- Ultrasound cavitation:

Mabel6 duo Ultracavitation and Multipolar RF System. DAEYANG MEDICAL, a Korean firm, produced it. It was utilized to treat all women in group B for 40 minutes, twice a week, for three months. The operator will adjust the instrument to 40 Khz using a touch screen, for a total treatment time of 40 minutes.

The belly was disinfected with alcohol and cotton while the woman was in a comfortable supine laying posture, and then conductive gel was placed to the abdomen. Following that, the ultra-hand piece's tip was inserted, kept perpendicular to the skin, and moved in a semi-rotating motion within the treated region.

Each woman in this group received two sessions per week for three months. To promote the purifying action of the liver and kidneys, ultrasound cavitation was applied for 20 minutes on the right side of the abdomen and then for 20 minutes on the left.

It is essential to advise the woman to begin drinking at least two to three liters of water daily the week before the session (**Figure 2**).



Fig. (2): Ultrasound cavitation application.

Ethical committee: The Faculty of Physical Therapy's Research Ethics committee gave its approval to the study protocol (No:P.T.REC /012/004058). Each participant completed a permission form when all information was received. Throughout its implementation, the study complied with the Helsinki Declaration.

Statistical analysis

Version 24.0 of the SPSS software was utilized to analyze the data. The mean \pm SD were used to express the results. In accordance with the test of normalcy, the unpaired t- test was used to compare the variables in the 2 groups. The paired t- test was used to compare

variables assessed in the same group before and after treatment. A P value ≤ 0.05 was deemed significant. Analysis of variance (T-test) was used to assess the effects of cryolipolysis and ultrasonic cavitation on post-menopausal abdominal obesity, with a significance level of 5% ($P \leq 0.05$).

RESULTS

Groups A and B did not significantly differ in terms of age, height, weight, or BMI ($p > 0.05$) (Table 1).

Table (1): Physical characteristics of both groups A and B

	Group A	Group B	p-value	t-value
	Mean \pm	Mean \pm		
Age (years)	54.7 \pm 3.2	54.9 \pm 2.2	0.843	0.119
Weight (Kg)	97.7 \pm 15	102.4 \pm 20	0.469	0.734
Height (cm)	164 \pm 8.5	168.7 \pm 5.7	0.089	1.764
BMI (kg/m ²)	36.5 \pm 5.9	35.9 \pm 5.1	0.779	0.283

*: Significant

Following treatment, both groups A and B showed a substantial drop in BMI, WC, hip circumference, WHR, and SFT. Pre-treatment as well as post-treatment, concerning BMI, WC, hip circumference, WHR, and SFT did not differ significantly between groups A and B (Table 2).

Table (2): Comparison between groups A and B regarding BMI, waist and hip circumference, waist to hip ratio and skinfold thickness

		Group A	Group B			
		Mean \pm SD	Mean \pm SD	F-value	P-value	S
BMI (kg/m ²)	Pre-treatment	36.5 \pm 5.9	35.9 \pm 5.1	0.080	0.779	S
	Post-treatment	31.7 \pm 4.5	32.3 \pm 5.5	0.082	0.780	S
	Percent of decrease (%)	13.2%	10%			
	P value	P<0.05*	P<0.05*			
Waist circumference (cm)	Pre-treatment	105.5 \pm 12.8	111.5 \pm 9.2	0.566	0.458	S
	Post-treatment	99 \pm 8.7	101.2 \pm 7.3	0.546	0.459	S
	Percentage of decrease (%)	6.2%	9.2%			
	P value	P<0.05*	P<0.05*			
Hip circumference (cm)	Pre-treatment	117 \pm 12.7	118.2 \pm 8	0.323	0.575	S
	Post-treatment	111 \pm 12.1	114.6 \pm 7.3	0.979	0.331	S
	Percentage of decrease (%)	5.1%	3%			
	P value	P<0.05*	P<0.05*			
Waist hip ratio	Pre-treatment	0.92 \pm 0.02	0.93 \pm 0.16	0.753	0.393	S
	Post-treatment	0.87 \pm 0.03	0.88 \pm 0.01	0.691	0.413	S
	Percentage of decrease (%)	5.4%	5.3%			
	P value	P<0.05*	P<0.05*			
Skinfold thickness (cm)	Pre-treatment	28.8 \pm 3.1	29.3 \pm 2.7	0.194	0.663	S
	Post-treatment	24.3 \pm 2.6	24.9 \pm 3.2	0.317	0.578	S
	Percentage of decrease (%)	15.6%	15%			
	P value	P<0.05*	P<0.05*			

*: Significant.

DISCUSSION

An excessive accumulation of fat surrounding and inside the abdominal cavity is referred to as central obesity, or abdominal obesity⁽⁹⁻¹¹⁾. In many nations, obesity has become a high priority on policy and program agendas due to its significant impact on public health and the economy. Preventing childhood obesity offers an especially strong call to action⁽¹²⁾.

The Cool Sculpting System, also known as cryolipolysis, is a non-invasive technique for reducing body fat selectively. This non-surgical method reduces subcutaneous fat without harming the surrounding tissues by using controlled cooling. Cryolipolysis is a proven method for safely and successfully reducing fat that was approved by the FDA 2010⁽¹³⁾. One of the most well-liked substitutes for liposuction in the treatment of adipose tissue spot reduction is cryolipolysis. This method is also becoming as the most popular noninvasive approach because to its simplicity and low risk of side effects⁽¹⁴⁾.

Skin tightening was seen in the cryolipolysis treatment region in addition to the expected fat decrease after treatment. Four months following treatment, the tightened skin on the patient's belly and flanks clung effectively to her new body shapes, despite the significant fat volume reduction causing skin laxity. After treatment, noticeable skin wrinkles that were present in pretreatment images disappeared⁽¹³⁾.

Ultrasonic cavitation vibrations propagate in the form of a wave in a medium, such as a liquid or solid. Ultrasound cavitation is an extremely effective method of fat loss because it transforms fat into liquid, which is then naturally removed by the urine, lymphatic system, and liver. Ultrasound cavitation is a revolutionary technique that may remove stored fat with the same effectiveness as liposuction but without the invasive component and related consequences⁽¹⁵⁾. The purpose of this study was to compare between the effect of cryolipolysis and ultrasound cavitation on post-menopausal abdominal adiposity.

The study's findings showed that both groups A and B showed a substantial reduction in SFT, WC, hip circumference, WHR, and BMI after treatment. BMI, waist WC, hip circumference, WHR, and SFT did not significantly differ between groups A and B either before or after treatment. The outcomes of this investigation are consistent with the findings of **Mulholland et al.**⁽¹⁶⁾ who showed that cryolipolysis and ultrasonic cavitation are safe, well-tolerated, and efficient non-invasive methods for reducing the thickness of abdominal fat. The WC and skin folds were reduced about equally by both methods, which are suitable for body contouring.

This study's findings also concur with those of **El-Desoky et al.**⁽¹⁷⁾ which revealed that clinical research demonstrated the safety and efficacy of both cryolipolysis and ultrasonic cavitation systems for body contouring and reducing abdominal adiposity. Participants' WC and skinfold measures decreased, indicating that both considerably decreased superfluous

subcutaneous adipose tissue from the abdomen. Regarding the decrease of fat thickness, there was no discernible difference between the two methods.

The findings of **Ferraro et al.**⁽¹⁸⁾ who claimed that cryolipolysis is a potent and well-established non-invasive technique for body contouring and fat thickness reduction, corroborate the findings of our investigation. After 3 months of cryolipolysis, the authors observed a 6.86 cm reduction in the circumference of the abdomen. Moreover, after two months of cryolipolysis therapy, **Shek et al.**⁽¹⁹⁾ observed a 4.9 mm reduction in abdominal fat thickness as assessed by a caliper. Similarly, **Macedo et al.**⁽²⁰⁾ said that cryolipolysis is advantageous in the management of excessive fat tissue in the belly or flanks as a result of fat modulation. Furthermore, **Sasaki et al.**⁽²¹⁾ showed that cryolipolysis is a pleasant, safe, and successful technique for reducing subcutaneous fat. Additional research by **Dover et al.**⁽²²⁾ and **Riobelle et al.**⁽²³⁾ has demonstrated that cooling non-invasively causes adipocyte death, which reduces the thickness of the fat layer. As adipocytes are eliminated through an inflammatory clearing process that peaks two to three months after being exposed to cold, inflammatory mediators cause phagocytosis, which is responsible for the removal of adipocytes and the loss of fat tissue. According to **Ferraro et al.**⁽¹⁸⁾, this eventually results in a gradual elimination of damaged adipocytes with little impact on blood and liver cholesterol levels.

The findings of this study are corroborated by **Mahgoub and Elshafey**⁽²⁴⁾ who discovered a substantial decrease in abdomen subcutaneous adipose tissue as determined by MRI with a 0.001 p-value, as well as a significant drop in WHR, SISF, and WC following 8 weeks of cryolipolysis. They ascribed this decrease to the targeted adipocytes' crystallization and cold ischemia damage, which causes apoptosis and a noticeable inflammatory response. As a consequence, the cells are eventually removed from the treatment location over the course of the next several weeks. Additionally, clinical research on cryolipolysis has demonstrated a 20%–40% decrease in fat. The thickness of the fat deposits in each place, the lifestyle maintained following treatment, and the individual will all affect the results. The best outcomes will be obtained by those who heed the aftercare instructions. The region treated, the thickness of the fat, and the individual all play a role. Alterations occur over a period of weeks. The greatest outcome is expected to be seen after 12 weeks, while alterations start to appear at about 2 weeks.

Nine out of ten participants in clinical studies reported an unquestionable decrease in the treated region 12 weeks after treatment. Sessions last up to forty-five minutes each. A three-dimensional camera was employed in one study to assess the degree of fat loss following cryolipolysis. The treated side showed a mean fat loss of 56.2±25.6 cc, while the control side experienced a mean fat loss of 16.6±17.6cc between baseline and the 2-month follow-up visit successively

($p < 0.0001$). The average difference in fat reduction between the treated and untreated groups was 39.6 cm at two months after treatment ⁽²⁵⁾.

According to **Sasaki *et al.*** ⁽²¹⁾ the mechanism of cryolipolysis is that ischemia-reperfusion injury exacerbates the initial insult of crystallization and cold ischemic injury caused by cryolipolysis, leading to the production of reactive oxygen species, stimulation of apoptotic pathways, and elevation of cytosolic calcium levels. **Preciado and Allison** ⁽²⁶⁾ emphasized how cutting fat thickness in treated areas decreased circumference. They explained this by stating that cryolipolysis-induced fat layer attrition is caused by adipocytes' deadly apoptotic reaction to freezing temperatures.

This study's findings are consistent with those of **Bani *et al.*** ⁽²⁷⁾ who discovered that ultrasonic cavitation caused a large, statistically significant (23%) reduction in the size of lipid vacuoles in adipocytes (Control: $15.654 \pm 942 \mu\text{m}^2$ & cavitation: $11.423 \pm 558 \mu\text{m}^2$, $P < 0.001$). Comparing subcutaneous fat samples collected during surgery from abdominal skin that had been ultrasound-pretreated or sham-treated produced similar results. The size of adipocyte lipid vacuoles was significantly reduced (-26%) in patients 1 and 2 (Biopsies were obtained 1 day after the last ultrasound application) (Control: $11.908 \pm 373 \mu\text{m}^2$ & cavitation: $8637 \pm 530 \mu\text{m}^2$, $P < 0.001$).

The study's results also corroborate those of a study by **Fatemi** ⁽²⁸⁾ that asserted that ultrasound cavitation reduces abdominal fat by ablating subcutaneous adipose tissue and producing molecular vibrations that induce rapid cell necrosis, raise local tissue temperature, and cause coagulative necrosis of the adipocytes, which in turn causes a decrease in the fat layer. Furthermore, **Morga *et al.*** ⁽²⁹⁾ demonstrated that all patients exhibited a substantial decrease in the thickness of subcutaneous fat in the treated area, proving that ultrasound was intended to employ mechanical (Non-thermal) energy to disturb fat cells. After three treatments, the average fat thickness was reduced by 2.28 to 20.80 cm. Because they were differently susceptible to the mechanical stresses caused by the ultrasound. The circumference was decreased by an average of 3.95 to 1.99 cm without causing harm to nearby tissues (Skin, blood, lymph vessels, muscles, and nerves). There were no negative consequences noted.

The results of the study disagree with **Akram *et al.*** ⁽³⁰⁾ who showed that both group A (Using ultrasound cavitation) and group B (Using cryolipolysis) showed a statistically significant decrease in central adiposity, as measured by BMI, abdomen fat%, and WC. However, neither group showed a statistically significant decrease in central adiposity 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, 11.07% reduction in abdominal fat%, and 5.59% enhancement in WC. Group B showed 3.62% reduction in BMI,

19.11% decline in abdominal fat% and 4.68% enhancement in WC. The cause of disagreement is that the sample size was very small and both genders also were included. Additionally, our findings contradict **Khedmatgozar *et al.*** ⁽³¹⁾ who evaluated the effectiveness of a non-invasive selective method for removing abdominal fat utilizing cryolipolysis and ultrasonic cavitation. It revealed that 30 subjects, aged 18 to 65 were randomly allocated to one of 3 groups out of a total of 90 females. During an 8-week period, participants in (Group 1) the control group were given a diet alone, patients in group 2 were given cryolipolysis and diet, and subjects in group 3 were given a combination of cryolipolysis, ultrasonic cavitation and diet. At the start, middle and conclusion of the trial, researchers measured anthropometric characteristics such as total body weight, body fat mass, fat-free mass, and abdominal circumference. Based on the findings, at the end of the intervention, each of the 3 groups showed 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.

LIMITATIONS

This study had some limitations as co-operation of women in conducting the procedure may affect the result. Physical status of women may affect the treatment and personal and individual differences between women.

CONCLUSION

It was determined that both cryolipolysis and ultrasonic cavitation had the same impact on lowering postmenopausal abdominal adiposity by decreasing BMI, WC, hip circumference, WHR, and SFT.

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