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ORIGINAL ARTICLES

Effect of ultrasound cavitation therapy as a non invasive approach on adipose tissue thickness in Egyptian women

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ABSTRACT

Excess body weight is the sixth most important risk factor contributing to the overall burden of disease worldwide. The mortality associated with excess weight increases as the degree of obesity and overweight increases**.** The main objective of this study was to measure the effect of ultrasound cavitation on adipose tissue thickness in women. A randomized, triple-blind, placebo-controlled trial of non invasive cavitation ultrasound therapy was carried out on obese women those attended at complementary medicine clinic, centre of excellent, National Research Center, Egypt. Sixty volunteer women of age between 30-50 years with a body mass index 25-35 kg/m^2 with buttock obesity (waist hip ratio less than 0.8) were included. All participants were undergone a balanced healthy diet for weight maintenance program. They were randomly assigned into two groups: 1) intervention group that receive cavitation ultrasound treatment, and 2) matching control group that receive a sham treatment; both for twice a week for 6 weeks. Local reduction of subcutaneous fat was measured by ultrasonography. The results revealed a significant decrease in fat thickness associated with a significant increase in waist hip ratio among women of intervention group after ultrasound cavitation treatment and weight maintenance program compared to control group. There were no significant differences between two groups regarding serum lipid profile including total cholesterol, HDL and LDL levels as well as weight loss at the end of the study. In conclusion ultrasound cavitation is a safe, effective therapy for reduction of fat tissue thickness and well-tolerated non invasive procedure for body contouring.

Key words: Adiposity, body contouring, cavitation ultrasound.

Introduction

Obesity or being overweight in human and most animals does not depend on body weight but on the amount of body fat to be specific as adipose tissue (Kershaw *et al.*, 2004).

Adipose tissue is a specialized connective tissue that functions as the major storage site for fat in the form of triglycerides. It is found in mammals in two different forms, white adipose tissue and brown adipose tissue. The presence, amount, and distribution of each vary depending upon the species (Albright and Stern, 1998).

Increased adipose tissue mass is the primary phenotypic characteristic of obesity. The amount and distribution of adipose tissue is associated with many of the adverse consequences of obesity, such as coronary artery disease and type 2 diabetes (Haslam and James, 2005; Brochu *et al.*, 2000).

It has been discovered that adipose tissue is not a single homogeneous compartment, but rather a tissue with specific regional depots with varying biological functions. Moreover, individual adipose tissue compartments have stronger associations with physiological and pathological processes than does total adipose tissue mass (Wei *et al.*, 2003)

Female sex hormone causes fat to be stored in the buttocks, thighs, and hips in women whereas men are more likely to have fat stored in the abdomen due to sex hormone differences (João *et al.*, 2011).

Ultrasound is cyclic sound pressure with a frequency greater than the upper limit of human hearing. Ultrasound is thus not separated from "normal" (audible) sound based on differences in physical properties, only the fact that humans cannot hear it. Although this limit varies from person to person, it is approximately 20 kilohertz (20,000 hertz) in healthy, young adults (Palumbo *et al.*, 2011).

Ultrasound Fat Cavitation (USFC) is the method in handling obesity, especially in destroying fat and shaping a particular part of the body. As one of the non-surgical correction method, USFC is preferred at decreasing the risk of complications due to obesity (Palumbo *et al.,* 2011; Ascher, 2010).

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USFC is a refinement of the Vibroliposuction (surgical liposuction utilizing ultrasound energy at the end of a probe that is inserted into the middle of fat layer). It is called refinement because Vibroliposuction is an invasive action inserting a strange object in the body. It exposes the body to risks of infection, bleeding and complications to fat emboli in blood vessel system (Hotta, 2010).USFC still uses ultrasound energy with an optimal power, but without invasive insertion. It is patched on the surface of skin where the site of fat layer (Fatemi, 2009).

The working principle of the USFC is a 20-70 kHz ultrasound energy will be emitted at certain depth in a convergent way and focused at a certain point to produce unlimited small vacuum bubbles (fat bubbling). These bubbles are pressured, and then they will break the bonds among fat cells, destroy the membrane walls of the fat to form "cavitations" (holes in the fat layer) and drain them into the lymphatic vessels to be excreted from the body. These fat-soluble particles changed into 3 new elements: triglycerides, free fatty acids water. Furthermore, triglycerides will be metabolized in the liver, free fatty acids will be used by muscles for energy and water will be disposed in the kidney (Brown *et al*, 2009).

Subject and Methods:

This is a triple-blind, randomized; placebo-controlled trial included 60 Egyptian overweight and obese healthy volunteer women with a buttocks obesity attended to complementary medicine clinic, centre of excellent, National Research Center, Egypt at the period between March to August 2013. They were randomly divided into two groups: 1) Control group included 30 women received a balanced healthy diet for weight maintenance and treated locally by sham cavitation ultrasound (non function) for 12 sessions (15 minute/session) along 6 weeks, and 2) Intervention group that included 30 women those received a balanced healthy diet for weight maintenance and treated locally by low frequency cavitation ultrasound (40Kz, 2.5watt/cm^2) LUVITRA model, DAEYANG MEDICAL company, Korea for 12 sessions (15 minute/session) along 6 weeks. Balanced healthy diet was conducted by calculating caloric daily intake according to age, height for weight maintenance for every woman as follows: step 1) calculating BMR: according to the equation [BMR = 655.1 + (9.563 x weight in kg) + (1.850 x height in cm – (4.676 x age in years)], and step 2) applying the Harris-Benedict principle, the method used to estimate the daily calorie requirements of an individual using their basal metabolic rate (BMR). The estimated value is then multiplied by a number that corresponds to the person's activity level. The resulting number is the recommended daily calorie intake to maintain current weight (Santos *et al.,* 2011).

Little to no exercise: Daily calories needed = BMR x 1.2
Light exercise (1-3 days per week): Daily calories needed = BMR x 1.375
Moderate exercise (3-5 days per week): Daily calories needed = BMR x 1.55
Heavy exercise (6-7 days per week): Daily calories needed = BMR x 1.725
Very heavy exercise (twice per day, extra heavy workouts): Daily calories needed = BMR x 1.9

Main outcome measures:

- Assessment of waist-hip ratio in all women before and after treatment.
- Measurement of fat thickness by ultrasound assessment before and after treatment in two groups.
- Assessment of blood level of cholesterol, HDL and LDL before and after treatment in two groups.

Inclusion criteria:

- Age 30-50 years old.
- WHR less than 0.8.
- Body mass index (BMI) 25-35 kg/m^2.
- At least 2.5 cm of fat thickness in the treatment area (able to pinch at least one inch).
- Informed consent from participants.

Exclusion criteria:

- Any associated chronic disease such as diabetes, hypertension, renal and hepatic diseases.
- High level of blood cholesterol and triglycerides.

Statistical Analysis:

Data were statistically analyzed using a standard program (SPSS), Echo Soft Corporation, USA, 1995. A student t- test was applied for conforming to normal distribution. Correlation coefficient (r) was used to determine the relationships between different quantitative values. For all tests, probabilities less than 0.05 were considered significant (Saunders and Trapp, 1995).

Results:

The obtained data in table 1 declared that there were no statistical significant differences between the two groups regarding basic characteristics including age, weight, height, BMI, serum cholesterol, HDL, LDL levels as well as WHR and fat thickness.

Table 1: Presents mean values of age, weight, height, BMI, serum cholesterol, HDL and LDL levels as well as WHR and fat thickness of both intervention and control groups before application of sessions and diet program.

Parameters	Control	Intervention	P- Value
Age (year)	36.3±3.59	37.3±4.99	P>0.05
Weigh (kg)	81.0±7.45	78.79±8.11	P>0.05
Height (cm)	165.87±6.86	160.43±6.99	P>0.05
BMI (kg/m^2)	29.47±1.98	30.67±3.05	P>0.05
Cholesterol (mg/dl)	182.47±15.26	182.77±14.37	P>0.05
HDL (mg/dl)	49.83±6.72	49.37±7.67	P>0.05
LDL (mg/dl)	95.8±11.79	95.3±10.84	P>0.05
WHR before treatment	0.738±0.027	0.734±0.033	P>0.05
Fat thickness (mm)	27.91±5.029	28.66±5.42	P>0.05

All data are expressed as mean ± standard deviation.

Also the results pronounced that either sham ultrasound cavitation or low frequency ultrasound cavitation has no significant differences regarding serum total cholesterol, HDL and LDL levels as well as weight loss at the end of sessions and diet program of this study (table 2).

Table 2: Presents mean values of serum total cholesterol, HDL and LDL levels as well as weight loss both intervention and control groups after sessions and diet program.

Parameters	Control	Intervention	p- value
Cholesterol (mg/dl)	180.73 ± 14.75	182.63 ± 13.91	P>0.05
HDL (mg/dl)	51.07 ± 6.49	48.43 ± 7.82	P>0.05
LDL (mg/dl)	95.1 ± 11.26	95.1 ± 10.85	P>0.05
weight loss (kg)	0.257 ± 0.28	0.297 ± 0.26	P>0.05

All data are expressed as mean ± standard deviation.

In addition, data in table 3 figure 2 and 3 illustrated a significant decrease in fat thickness matched with a significant increase in WHR among women of intervention group after treatment by ultrasound cavitation and weight maintenance program.

Table 3: Mean values of fat thickness and WHR changes intervention group before and after sessions and diet program.

Variable	Before	After	p- value
Fat thickness (mm)	28.66 ±5.42	13.76 ±3.48	P<0.001
WHR	0.734±0.033	0.765±0.036	P<0.001

All data are expressed as mean ± standard deviation.

The data recorded in table 4 and figure 1, and 2 pointed that women in intervention group showed a significant lower fat thickness with higher WHR after treatment compared to those of control group.

Table 4: Comparison of fat thickness, WHR and fat loss change between control and intervention groups.

Variable	Control	Intervention	p-value
Fat Thickness (mm)	27.91 ± 5.029	13.76 ±3.48	P<0.001
WHR	0.734 ± 0.029	0.765 ± 0.036	P<0.001
Fat thickness loss (mm)	0.033 ± 0.0.076	15.29 ± 4.23	P<0.001

All data are expressed as mean ± standard deviation.

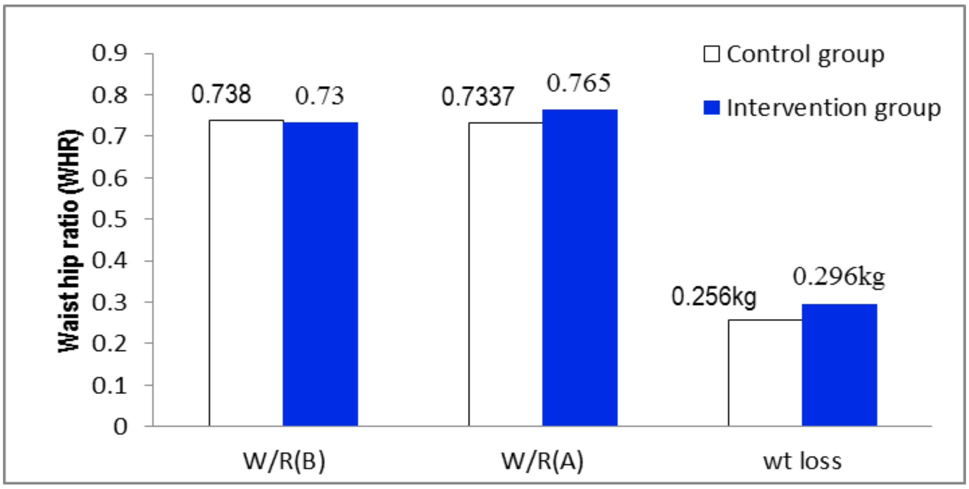

Fig. 1: Shows the effect of sessions of cavitation ultrasound and weight maintenance diet on waist hip ratio (WHR) and weight loss (kg) in intervention group before(B) and after(A) treatment in comparison with weight maintenance diet and non function cavitation sessions in control group.

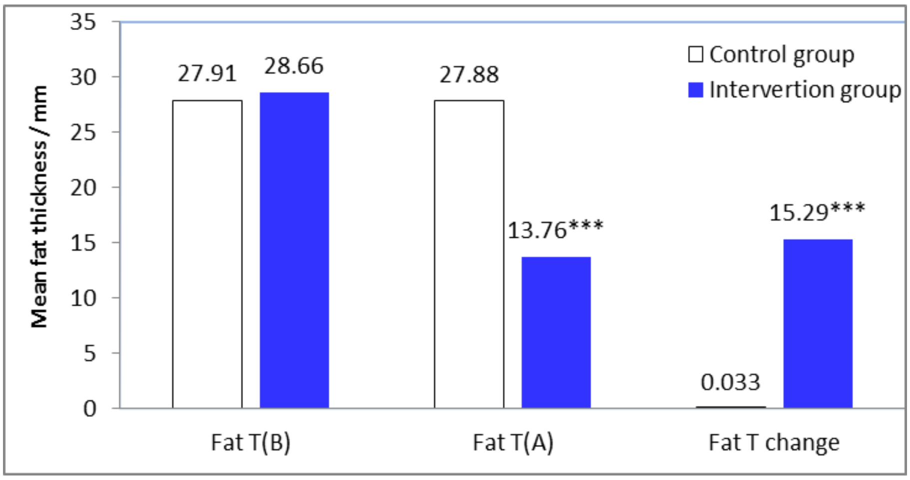

Fig. 2: Shows the effect of sessions of cavitation and diet maintenance on fat thickness and fat loss (mm) in intervention group before and after treatment in comparison with control group.

Discussion:

Low frequency ultrasound cavitations treatment is a relatively new procedure offering non-invasive, painless reduction of unwanted fat deposits (Brown *et al.*, 2009). Energy is released in the form of heat (minor effect) and pressure waves (major effect). As membranes of fat cells do not have the structural capacity to withstand such vibrations, the effect of cavitations easily breaks them while sparing vascular, nervous and muscular tissue (Phelps and Leighton, 1997).

In this study, women in intervention group showed a significant lower fat thickness with higher WHR after treatment by cavitations ultrasound compared to women in control group. Our study demonstrates the safety of ultrasound cavitations proved by absence of significant differences in serum cholesterol, HDL and LDL before and after treatment that is consistent with Gadsden *et al.* (2010). Fourteen women reach the desirable effect before the twelve sessions in this study. On the other hand, by comparing the two groups, there was no significant change in weight loss.

Very few published studies have dealt with the biological effects of such therapies on human adipose tissue. For lower levels of ultrasonic energy, interruption of the adipocytic membranes was evident both in the surface and in the deeper cutaneous and subcutaneous layers, with focal dissolution and homogenization of the surface dermal fascia. For higher levels of ultrasonic energy, alterations of the adiposities and of the collagen fibers were greater, resulting in the dissolution of the cells and of the interlobular fibrous septa. Both effects were amplified by tumescent saline infiltration. The histological lesions demonstrated in adipocytes confirm the theoretical premises of a possible usefulness in the treatment of localized adiposis. The alterations observed in the connective stroma could have positive effects on the structural reorganization and consequently on the in vivo external appearance of the treated areas (Pugliese *et al.*, 2013). Moreover, the overall effects of ultrasound irradiation did not appear immediately after treatment but persisted over time, being significantly more relevant at 18 h from the end of ultrasound irradiation. Ultrasound exposure had been shown to induce apoptosis as shown by the appearance DNA fragmentation. Accordingly, ultrasound treatment led to down-modulation of procaspase-9 expression and an increased level of caspase-3 active form Palumbo *et al.* (2011).

Similar studies are scarce; however Ferraro *et al.* (2008) observed the effects of ultrasound waves at different frequencies on abdominal fat tissue. External ultrasound-assisted lipectomy (XUAL) via both histologic and immune histochemic examinations was used to assess adipose tissue alterations, including cells and collagen fibers; then they demonstrated that with the XUAL technique, ultrasound at 1 MHz does not induce cellular alterations. In contrast, both 2- and 3-MHz frequencies are capable of causing complete fat tissue disruption, including destruction of adipose cells and collagen fibers.

Our results are consistent with a randomized, sham controlled, single-blinded trial that reported by Jewell *et al.* (2011and 2012) who evaluated the efficacy through 12 weeks and safety through 24 weeks after HIFU (high intensity focus ultrasound) treatment. Also, Gadsen *et al.* (2010) reported 3 studies that investigated the use of the HIFU in human patients. The histopathology revealed well-demarcated disruption of adiposities within the targeted subcutaneous adipose tissue. Serum lipids were measured over 4 weeks and did not demonstrate any clinically significant changes in the serum levels of free fatty acids, cholesterol, or triglycerides. The adverse events were temporary treatment discomfort, edema, erythema, dysesthesia, and ecchymosis. There were no serious device-related adverse events.

A recent study carried out by Wallner *et al.* (2013) confirmed that, the use of subcutaneous adipose tissue topography (SAT-Top) is more effective than BMI in assessing obesity in physically active people and young adults. These results suggest that subcutaneous fat patterns are a better screening tool to characterize fatness in physically active young people.

Nazanin and Michael (2013) reported the adverse effects of high frequency focused ultrasound included mild to moderate, ecchymosis, discomfort and edema.

Our results showed a significant increase in WHR after treatment by ultrasound cavitation that indicted the efficacy of ultrasound cavitation in reduction of hip circumference that represented a great challenge in fat reduction by diet and exercises. Prachi *et al.* (2012) reported that upper body subcutaneous fat and visceral fat increase and decrease proportionately with a short-term weight gain and loss, whereas a gain of lower-body fat does not relate to the loss of lower-body fat. The loss of lower-body fat is attributed to a reduced fat cell size, but not number, which may result in long-term increases in fat cell numbers. Moreover, Guo *et al.* (1997) reported that upper body and visceral fat are also generally more responsive to lipolytic stimuli than lower-body adiposities. Further studies on larger sample size population for more addressing the efficacy, safety and biological effects of cavitation ultrasound on adipose tissue are warranted.

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