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Effect of Cryolipolysis and Electrolipolysis on Postmenopausal Abdominal Adiposity

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Abstract

Background: Menopause is a normal condition that all women experience as they age. Women generally accumulate more intra-abdominal adipose tissue as they go through menopause. Although diet and exercise may be effective in controlling obesity, cosmetic procedures may still be necessary to remove localized adiposity.

Aim of the Study: This study was conducted to determine the effect of cryolipolysis and electrolipolysis on post-menopausal abdominal adiposity.

Methodology: Fourty five post menopausal women participated in this study. Their age ranged from 45 to 55 years, patients were distributed randomly into three equal groups (A,B&C). Patients of group (A) received cryolipolysis, patients of group (B) received electrolipolysis and patients of group (C) received cryolipolysis and electrolipolysis. Evaluation was done by measuring waist circumference (by tape measurments), supriliac skin fold (by body fat caliper) and body weight, waist hip ratio, body mass index, abdominal fat percentage (by bioelectrical impedance analysis).

Results: There was a significant decrease in waist circumference, supriliac skin fold, body weight, waist hip ratio, body mass index and abdominal fat in the three groups A, B and C. when comparing between pre and post study results.On comparing results of the three groups post treatment; there were significant differences in WC, WHR and trunk fat % in group (A) than group (B) and non significant differences between SISF, BW and BMI in group (A) than group (B), also there were significant differences in BW, BMI, and SISF in group (A) than group (C), while non significant differences between WC, WHR and trunk fat % in group (A) than group (C) and finally there were significant differences in BW, BMI, WC, SISF, WHR and trunk fat % in group (B) than group (C).

Conclusion: From the results of the present study it can be concluded that Cryolipolysis and Electrolipolysis are effective in reducing abdominal adiposity in post-menopausal women.

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Key Words: *Cryolipolysis – Electrolipolysis – Low caloric Diet*

Introduction

THE term "menopause" can describe any of the changes a woman goes through either just before or after she stops menstruating, marking the end of her reproductive period. A woman is born with a finite number of eggs, which are stored in the ovaries. The ovaries also make the hormones estrogen and progesterone, which control menstruation and ovulation. Menopause happens when the ovaries no longer release an egg every month and menstruation stops **[1]**.

Extra weight puts added pressure on the spine, which can cause pain and degenerative changes in the vertebral column and even back strain and herniated disc. Central obesity is associated with a statistically higher risk of heart disease, hypertension, insulin resistance and diabetes mellitus type 2 **[2]**.

Postmenopausal obesity compounds the situation leading to increased rates of hypertension, diabetes mellitus, coronary artery disease and mortality. Additional consequences of obesity may include hormone-dependent cancer, gallstones, nephrolithiasis, and osteoarthritis with increased mortality **[3]**.

The Electro-Lipolysis (CMNS6 needle stimulator) is known as a system that uses of thin disposable needles, connected to small electrodes, to insert under the skin to transmit to the tissues a light current that accelerates the activity of the cells. Electrolipolysis techniques usually involve the reduction of the number of adipocytes, mostly

by inducing cellular death which may produce an inflammatory response and, in the long term, increase the number of adipose cell as a direct rebound reaction [4].

Cryolipolysis is a new, noninvasive treatment option that may be of benefit in the treatment of excess adipose tissue after menopause. Cryolipolysis is a new technology that uses cold exposure, or energy extraction, to result in localized panniculitis and modulation of fat. Presently, 3max cool shaping device is FDA cleared for skin cooling, as well as various other indications, but not for lipolysis. There is, significant reductions in the superficial fat layer thickness, ranging from 20% to 80%, following a single cryolipolysis treatment. The decrease in fat thickness occurs gradually over the first 3 months following treatment, and is most pronounced in patients with limited, discrete fat bulges. Erythema of the skin, bruising, and temporary numbness at the treatment site are commonly observed following treatment with the device, though these effects largely resolve in approximately 1 week. To date, there have been no reports of scarring, ulceration, or alterations in blood lipid or liver function profiles [5].

Patients and Methods

This study was conducted during period from September 2016 to May 2017 in the Outpatient Clinic of Obstetrics and Gynaecology, Al Qasr Al-Aini to investigate the effect of electrolipolysis and cryolipolysis on postmenopausal abdominal adiposity.

Participants:

Fourty five female patients at least 2 years post menopause participated in this study, their ages ranged from (45 to 55 years), their BMI was >30kg/m^2. They all suffer from abdominal obesity as their waist circumference was >90cm and their waist hip ratio was >0.85. They were assigned randomly into three equal groups (A,B&C).

Group (A): Received cryolipolysis (3 sessions, once every 6 weeks, for 3 months) and low calorie diet (1200 Kcal/day).

Group (B): Received electrolipolysis for 60 minutes (24 sessions, twice per week, for 3 months) in addition to low caloric diet as in group (A).

Group (C): Received cryolipolysis and electrolipolysis in addition to low caloric diet (1200 Kcal/day).

Assessment was done by Tape measurments (for measuring waist circumference), body fat caliper (for measuring supriliac skin fold) and Bioelectrical impedance analysis (for measuring body weight, waist hip ratio, body mass index and abdominal fat percentage).

Ethical consideration; the purpose, nature and potential risks of the study were explained to all patients. All patients signed a consent form prior to participation in the study.

Exclusion criteria:

Women with malignancies or receiving radiotherapy, women with kidney or liver disease, or having circulatory dysfunction were excluded from the study. Also women with fatty liver, post-surgical abdominal scar, metabolic disorders or implanted medical device (as pace maker).

Methods: Evaluative procedures:

Assessment procedure was performed for all patients in the three groups before and after three months of treatment.

1- Tape measurement: Was used to measure waist circumference pre and post treatment.

2- Body fat caliper: Was used to measure abdominal skin fold thickness pre and post treatment.

3- Bioelectrical impedance analysis (IN BODY 230):

Bioelectrical impedance analysis (BIA) is a widely used method for estimating body composition. The technology is relatively simple, quick, and noninvasive.

Despite a general public perception that BIA measures “body fat,” the technology actually determines the electrical impedance of body tissues, which provides an estimate of total body water (TBW). Using values of TBW derived from BIA, one can then estimate fat-free mass (FFM) and body fat (adiposity).

In body 230 model MW 160 is a Korean made device, it is a highly accurate device with electrode rating 330 microamperes and widely used is assessing obesity.

These data were collected and recorded in a recording data sheet.

Treatment procedures:

A-*Electrolipolysis group:*

Procedures involves inserting 6 needle electrodes to the abdomen set at automatic polarity

mode reversal, rectangular waveform, 30Hz, intensity was determined by sensitivity and tolerance of patient not exceeding 400m amps. Electrodes were placed in the abdominal region above and below umbilicus, distribute of pairs in a way that all treated area to be covered, with the distance between them 6cm. The treatment started with contraction time for four seconds followed by another four seconds of relaxation time, the machine was adjusted at 20 pulses/minutes and set manually by the investigator based visual inspection of the contraction obtained (Up to maximum approximately 400mA) the machine automatically switch off when the session time ends (60 minutes). Women received two sessions every week for 3 months.

B- *Cryolipolysis:*

The abdomen was divided into three main areas one on the right, one on the left and another on the center.The fatty area to be treated first was covered with a cool gel pad in order to protect the skin. A large cup like applicator was then applied over the area to be treated. A vacuum is then applied through this cup applicator, which ultimately sucks in the roll of fat that will be treated. The patient feel a firm pulling sensation during this action. In the first ten minutes the temperature within the cup was then gradually lowered until it gets to a predetermined temperature of about –7 or –8 degrees Celsius, thereby slowly freezing the fat cells within the roll of fat. The cup applicator remained in contact, via the suction process, with the treated roll of fat for half an hour, each area that is treated with any single cup applicator required 60 minutes of cooling, each patient received one session every 4 weeks for 3months (a total of three sessions).

Statistical analysis:

Descriptive statistics and ANOVA-test were conducted for comparison of the mean age of the three groups, One way ANOVA test was conducted for comparison of weight, BMI, waist circumference, supra iliac skin fold, W/H ratio and trunk fat between the three groups. Paired *t*-test was conducted for comparison between pre and post treatment mean values of weight, BMI, waist circumference, supra iliac skin fold, W/H ratio and trunk fat in each group, The level of significance for all statistical tests was set at $p<0.05$. All statistical tests were performed through the statistical package for social studies (SPSS) version 19 for windows. (IBM SPSS, Chicago, IL, USA).

Results

Forty-five postmenopausal females with abdominal adiposity participated in this study. Subjects were divided into three groups, group A,B, and C, fifteen patients in each group. Group A received cryotherapy and low-calorie diet. Group B received electrolipolysis and the low-calorie diet. Group C received cryotherapy, electrolipolysis and the low-calorie diet.

The results showed that there were significant reduction in waist circumference (WC) by 87.96 ±7.8, 94.95±6.65, and 85.06±7.69cm respectively, suprailiac skinfold (SISF) by 27.7 ±4.77, 29.28± 4.69, and 22.89±4.58mm in groups A,B & C respectively, body weight (BW) by 78.11 ±9.45, 82.02 ±4.47, and 69.42±10.43kg in goups A,B & C respectively, mass index (BMI) by 30.97 ±2.76, 32.23±2.94, and 27.88±3.82 kg/m^2 in groups A,B & C respectively, waist hip ratio (WHR) by 38.26±2.96, 43.73±2.08, and 37.74±3.01% and trunk fat % by 0.85 ±0.04, 0.9±0.04, and 0.84±0.04 in groups A,B & C respectively (Table 1).

On comparing results of the three groups post treatment, there were significant differences between the three groups where: Between group (A) and group (B) there were significant differences in WC, WHR and trunk fat % and non significant differences between SISF, BW and BMI (Table 2), while between group (A) and group (C) there were significant differences in BW, BMI, and SISF (Table 3), while non significant differences between WC, WHR and trunk fat % and finally between group (B) and (C) there were significant differences in BW, BMI, WC, SISF, WHR and trunk fat % (Table 4).

Discussion

This study was conducted to investigate the effect of electrolipolysis and cryolipolysis on post menopausal abdominal adiposity.

The results revealed that there was a reduction in weight post study when compared to pre- study results in groups (A&B&C) after the end of study. More than a few mechanisms can explain that reduction. One of them includes the fact that caloric restriction is often associated with depletion of glycogen storage as well as a decline in body fat especially in the central body region. These effects were documented by de Luis et al., [6] who proved that hypocaloric diet can cause reduction of anthropometric measures (weight, body mass index, waist circumference and waist/hip ratio) together with an improvement in metabolic profile.

Table (1): Mean values and standards deviations of anthropometrics and bio-electrical impedance measurements before and after treatment in three groups.

			Mean	SD	X diff	% of change	*t*-test	*p*-value	Sig.
Weight (Kg):	Group A	After	85.37	12.38	7.26	8.5	6.35	0.0001	S
		Before	78.11	9.45					
	Group B	After	86.46	4.58	4.44	5.13	10.55	0.0001	S
		Before	82.02	4.47					
	Group C	After	84.33	11.84	14.91	17.68	9.1	0.0001	S
		Before	69.42	10.43					
BMI:	Group A	After	33.78	3.17	2.81	8.31	7.64	0.0001	S
		Before	30.97	2.76					
	Group B	After	33.96	2.94	1.73	5.09	11.05	0.0001	S
		Before	32.23	2.94					
	Group C	After	33.81	3.2	5.93	17.53	9.21	0.0001	S
		Before	27.88	3.82					
Waist circumference (cm):	Group A	After	101.76	8.02	13.8	13.56	21.15	0.0001	S
		Before	87.96	7.8					
	Group B	After	100.06	4.38	5.11	5.1	5.13	0.0001	S
		Before	94.95	6.65					
	Group C	After	101.76	8.02	16.7	16.41	22.77	0.0001	S
		Before	85.06	7.69					
Suprailiac skin fold (mm):	Group A	After	30.72	4.71	3.02	9.83	15.37	0.0001	S
		Before	27.7	4.77					
	Group B	After	31.64	5.06	2.36	7.45	20.61	0.0001	S
		Before	29.28	4.69					
	Group C	After	30.71	4.7	7.82	25.46	11.22	0.0001	S
		Before	22.89	4.58					
W/H ratio:	Group A	After	0.95	0.04	0.1	10.52	9.9	0.0001	S
		Before	0.85	0.04					
	Group B	After	0.94	0.04	0.04	4.25	5.99	0.0001	S
		Before	0.9	0.04					
	Group C	After	0.95	0.04	0.11	11.57	9.66	0.0001	S
		Before	0.84	0.04					
Trunk fat %:	Group A	After	45.53	2.22	7.26	15.96	10.01	0.0001	S
		Before	38.26	2.96					
	Group B	After	46.29	1.9	2.56	5.53	18.24	0.0001	S
		Before	43.73	2.08					
	Group C	After	45.53	2.22	7.79	17.1	11.48	0.0001	S
		Before	37.74	3.01					

X-diff: Mean difference. S: Significant. SD: Standard deviation. *p*-value: Probability value.

Table (2): Comparison between anthropometrics measurements and bio-electrical impedance for groups (A&B) after treatment

	Group A	Group B	Diff	*p*-value	Sig.
Weight	78.11±9.45	82.02±4.47	–3.91	0.42	NS
BMI	30.97±2.76	32.23±2.94	–1.26	0.53	NS
Waist circumference (cm)	87.96±7.8	94.95±6.65	–6.99	0.03	S
Suprailiac skin fold (mm)	27.7±4.77	29.28±4.69	–1.58	0.62	NS
W/H ratio	0.85±0.04	0.9±0.04	–0.05	0.02	S
Trunk fat %	3 8.26±2.96	43.73±2.08	–5.47	0.0001	S

Table (3): Comparison between anthropometrics measurements and bio-electrical impedance for groups (A&C) after treatment.

	Group A	Group C	Diff	*p*-value	Sig.
Weight	78.11±9.45	69.42±10.43	8.69	0.02	S
BMI	30.97±2.76	27.88±3.82	3.9	0.03	S
Waist circumference (cm)	87.96±7.8	85.06±7.69	2.9	0.53	NS
Suprailiac skin fold (mm)	27.7±4.77	22.89±4.58	4.81	0.02	S
W/H ratio	0.85±0.04	0.84±0.04	0.01	0.58	NS
Trunk fat %	38.26±2.96	37.74±3.01	0.52	0.86	NS

Table (4): Comparison between anthropometrics measurements and bio-electrical impedance for groups (B&C) after treatment.

	Group B	Group C	Diff	*p*-value	Sig.
Weight	82.02±4.47	69.42±10.43	12.6	0.001	S
BMI	32.23±2.94	27.88±3.82	4.35	0.002	S
Waist circumference (cm)	94.95±6.65	85.06±7.69	9.89	0.002	S
Suprailiac skin fold (mm)	29.28±4.69	22.89±4.58	6.39	0.002	S
W/H ratio	0.9±0.04	0.84±0.04	0.06	0.001	S
Trunk fat %	43.73±2.08	37.74±3.01	5.98	0.0001	NS

While the decrement in Waist circumference and waist hip ratio may be explained by decrement in body fat mass in the abdominal region. It may also be related to regional change in LPL activity in the abdominal fat area, this lead to mobilization of FFA from centrally distributed adipose tissue, this is in agreement with Astrup and Rossner [7] who showed that post menopausal women appear to lose more fat from abdominal region during diet regimen.

The results of this study backed the findings of Ferraro et al. [8] who stated that cryolipolysis is a powerful, and well-endured non-invasive methodology for body contouring and the reduction of fat thickness. The authors recorded a decrease in the abdominal circumference by 6.86cm after three months of using cryolipolysis. Moreover, Shek et al., [9] recorded a 4.9mm decrease in fat thickness measured by a caliper following 2 months of treatment by cryolipolysis in the abdominal region. Likewise, Macedo et al., [10] claimed that cryolipolysis is beneficial in the treatment of over abundant fat tissue in the flanks or abdomen area as a consequence of fat modulation. Additionally Dierickx et al., [11] and Sasaki et al., [12] proved that cryolipolysis is a safe, comfortable, and effective method for subcutaneous fat reduction. Other studies by Dover et al., [13] and Riobelle et al., [14] have shown that cooling non-invasively induces adipocyte death that leads to a lessening in fat layer thickness while the loss of adipose tissue volume occurs gradually over time as the adipocytes are removed through an inflammatory clearing process that peaks within 2-3 months after exposure to cold, then inflammatory mediators trigger phagocytosis which accounts for the removal of adipocytes and the loss of fat tissue. Ferraro et al., [8] added that over time, this leads to a slow removal of destroyed adipocytes, with no consequent effect on lipid levels in the bloodstream and liver.

Our study results were compatible with El-Desouky et al., [15] who used cryolipolysis for 2 months and found a significant decrease of 5.8% in body weight, BMI showed a significant 5.83% reduction, WC was significantly reduced and the SISF was significantly reduced by 17.41% post treatment. This was no different from Mahgoub and El Shafey [16] results who also found a significant reduction in WHR, SISF and WC after 8 weeks of using cryolipolysis in addition to a significant decrease in abdominal subcutaneous adipose tissue measured by MRI with a 0.001 *p*-value, they attributed this reduction to crystallization and cold ischemic injury of the targeted adipocytes that induce apoptosis of these cells and a pronounced inflammatory response, resulting in their eventual removal from the treatment site within the following several weeks.

Another mechanism as proposed by Sasaki et al., [12] was that the initial insult of crystallization and cold ischemic injury induced by cryolipolysis is further compounded by ischemia-reperfusion injury, causing generation of reactive oxygen species, elevation of cytosolic calcium levels, and activation of apoptotic pathways. Preciado [17] highlighted the decrease in the circumference in treated regions by reducing fat thickness, and

explained it as cryolipolysis-induced fat layer attrition results from the fatal apoptotic injury of adipocytes when exposed to cold temperatures.

Also, our results are completely supported by Krueger et al., [18] who demonstrated a reduction of up to 1 cm or 40% of abdominal fat layer thickness after a single exposure without harming the overlying skin and Manstein et al., [19] found a reduction in abdominal fat thickness measurd by abdominal ultrasonography and explained this reduction to lipid-laden mononuclear inflammatory cells and local thickening of fibrous septae at 2 weeks post-procedure implicating apoptosis and phagocytosis.

Concerning electrolipolysis group, Tochikubo et al., [20] who used transcutaneous electric abdominal muscle stimulation (3000 muscle contractions /day) for four weeks to treat obese subjects, those subjects showed significant reduction in body weight and intra-abdominal visceral fat. Also, Irving et al., [21] reported that when a muscle contracts as a result of electrical stimulation, the chemical changes taking place within the muscles are similar to those associated with voluntary contractions in normal exercising. These chemical reactions which results from muscle contractions utilize glycogen fat and other nutrients stored in the muscles. Also, it enhances energy consumption, carbohydrate oxidation and whole body glucose uptake.

Other explanation about the effect of electrolipolysis was mentioned by Kantor et al., [22] who reported that electrical stimulation stimulates the adrenergic interstitial nerve endings that liberates more catecholamine hormone which enhance the adenilate cyclase to convert adenosine triphosphate to cyclic adenosine monophosphate thus activating lipasis.

In contrast Clifton et al., [23] who found that in obese post menopausal women, weight loss does not affect the regulation of regional fat metabolism and a greater tonic inhibition of basal lipolysis by endogenous adenosine that may increase the activity of adipose tissue LPL after weight loss and predispose older women to develop abdominal obesity. In addition Mekawy and Omar [24] found a significant reduction in fat % by electrolipolysis in premenopausal obese women, they explained that the change in fat mass may be due to several possible mechanisms including, shifting in substrate utilization, decrease in proteolytic counter regulatory hormones and increase in lipo-protein lipase activity which could explain the change in fat mass.

Our findings are consistent with Abdul Hameed et al., [25] who found a significant reduction in SISF, BMI, WC and BW following electrolipolysis for four weeks. Our findings are also consistent with those of previous studies like Paula et al., [26], Azevedo et al., [27] and Couto et al., [28] who observed in the experimental groups compared to the control group, a tendency to decrease in fat mass estimated by skinfolds (abdominal folds and suprailiac), hip circumference and BMI with minimal changes in lean body mass, which supports an effect of adjuvant electrolipolysis in mass reduction fat overall.

Our results also came with those from the study done by Stevens et al., [29] it found out that simultaneously combining two separate actions; cryolipolysis through hypothermal action at a temperature below 0°C and electro-stimulation using specific currents has a slimming draining effect which enhances reduction of localised fat deposits and better distribution of their volume.

Conclusion:

Cryolipolysis and Electrolipolysis could be used as non invasive effective methods in reducing abdominal fat in postmenopausal women.

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