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Original Research Article

EFFICACY OF ULTRASOUND CAVITATION, TRIPOLLAR RADIO FREQUENCY LIPOLYSIS AND COMBINATION THERAPY ON ABDOMINAL ADIPOSITY

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ABSTRACT

Background: Central obesity or increased intra-abdominal fat is associated with a statistically higher risk of heart disease, hypertension, insulin resistance, and diabetes mellitus type 2.

Objective: This study was conducted to investigate and compare the effectiveness of tripollar radiofrequency lipolysis (RF), ultrasound (US) cavitation and their combination on abdominal subcutaneous fat thickness and waist circumference (WC) in patients with abdominal adiposity.

Subjects: Thirty subjects suffering from localized fat deposits at the abdominal area with age ranged from 25-50 years old, BMI more than 30 kg/m^2 assigned randomly into three equal groups: Group (A) consisted of 10 subjects with mean age and BMI were 38.7±6.63 years and 33.55±1.31 kg/m^2 respectively. Group (B) consisted of 10 subjects with mean age and BMI were 34.3±7.76 years and 33.57±1.57kg/m^2 respectively. Group (C) consisted of 10 subjects with mean age and BMI were 34.3±7.76 years and 32.99±3.73 kg/m^2 respectively.

Methods: Group (A) received US cavitation (AC 220 Volt. 40 KHz) twice weekly for 10 sessions. Group (B) received tripollar RF (AC 220 Volt .1MHZ. 50 Watts) twice weekly for 10 sessions. Group (C) received combination therapy (both tripollar RF and US cavitation) twice weekly for 10 sessions. Subjects in all groups were assessed using ultrasonography and tape measurement before treatment then after treatment after 10 sessions to measure subcutaneous fat thickness and WC.

Results: Showed that there was statistical significant difference between pre and post treatment within each group (A, B and C) for abdominal subcutaneous fat thickness and WC. But there was a non-statistical significant difference between group A and group C; also, there was no statistical significant difference between group A and group B, while, there was a statistical significant difference between group B and group C in management of abdominal adiposity.

Conclusion: Ultrasound cavitation, tripollar RF and their combination were effective methods for management of abdominal adiposity, but combination therapy were the most effective.

KEY WORDS: Abdominal Adiposity, Ultrasound Cavitation, Tripollar Radiofrequency, Combination therapy, Waist Circumference.

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INTRODUCTION

Obesity is often defined simply as a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health may be impaired [1].

Obesity consists of excessive fat deposits throughout in the body, whereas central obesity or abdominal adiposity denotes excessive fat in the mid body region, much of it in the intra-abdominal area [2].

The pattern of fat distribution in the human body is affected by sex, diet, level of physical activity and mostly by genetics. One aesthetic problem for individuals, who achieve modest or even dramatic weight loss due to a diet control program combined with physical exercise, is the inability to eliminate localized fat deposits from specific anatomical sites, such as the abdomen, buttock and thighs [3].

With the wide spread use of topical and oral medications for the treatment of obesity with its side effect and lack of accuracy for the most of these medications, dermato-functional physiotherapy has efficient resources to fight these problems [4].

Ultrasound (US) cavitation improves the appearance of body shape, focused therapeutic US is used to reduce adipose tissue and its efficacy was determined by the change in fat thickness [5].

Ultrasonic waves create compression cycles that exert positive pressure and expansion cycles that exert negative pressure. This pushing and pulling effect can lead to rupture of fat cells and eventually cavitation. Focusing this ultrasonic energy into the deeper fat layers can lead to cavities in the fat and theoretically reduction of the overall thickness of the adipose layer [6].

Radiofrequencies (RF) treatments have been accepted as one of the most popular and promising procedures for the treatment of cellulite, skin tightening and body sculpting. TriPollar RF technology provided beneficial effects on the reduction of abdomen and thigh circumferences and an overall improvement in the appearance of cellulite [7].

Ultrasound cavitation and RF lipolysis are being from the available noninvasive methods of adipose tissue removal, these devices have been developed to remove or reduce unwanted local subcutaneous fat, and combination of these treatment modalities for fat disrupter for body contouring was used to achieve synergetic effect [8].

Based on the previous studies, Tripollar RF lipolysis, US cavitation have an effect on local subcutaneous fat thickness and waist circumference (WC) in patient with abdominal adiposity, but there is gap in comparing the effect of these two modalities and their combination on local subcutaneous fat thickness and WC in patients with abdominal adiposity, so this study was conducted to cover this gap.

MATERIALS AND METHODS

Subjects: Thirty patients suffering from localized fat deposits at the abdominal area. They were recruited from Mallawy hospital outpatient clinics during period from first of February 2016 till April 2016. Their ages ranged from 25-50years old, Egypt, Elminya. Body mass index (BMI) was more than 30kg/m^2 and their WC was more than 90 cm in male and 80 cm in female. The patients were excluded if they had serious diseases, such as heart disease, gastric ulcer, serious gastropathy, duodenal ulcer, and uncontrolled diabetes or hypertension. They were divided randomly and equally into three equal groups (Maximize statistical power). Group (A) Ten patients managed with US cavitation for ten sessions. Group (B) Ten patients managed with tripollar RF lipolysis for ten sessions. Group (C) Ten patients managed with combination of US cavitation and tripollar RF lipolysis for ten sessions. Randomization: The participants were randomly allocated to each group. The randomization was done by a colleague independent and blind to the study using concealed envelopes within which the group description was randomly placed within them.

Procedures

Evaluation procedures

Ultrasonography examination: Ultrasound imaging is based on the different acoustic properties of different tissues. During measurement; the patient was in a supine position. It

was necessary to remove any air bubble prior to examination by immersing the tip of the probe in saline and massaging the tip very gently with a bent swab. When imaging, the transducer was positioned perpendicular to the skin to avoid obliquity and to prevent errors during determination of skin thickness. A thick layer of ultrasound gel was applied to improve near field visibility and avoid tissue compression, which would alter measurements of tissue thickness. Ultrasonographic examination was done by radiology specialist at 2 times for all subjects before and after treatment sessions [9]. The technique which was used measured the distance between the epidermis and the superficial fascia (Camper's fascia) separating the superficial and deep subcutaneous layer at a specific and consistent distance from an anatomical landmark of abdomen. Each measurement was evaluated on two planes by radiologist: the first plane was parallel to the long axis of the abdomen, and the second plane was perpendicular to the first one. Ultrasonographic examination was done by radiology specialist at 2 times for all subjects before and after treatment sessions [10].

Waist circumference measurement: Abdominal circumferences was measured in centimeter with the patient in standing position by applying a plastic tape at the midpoint between the rib cage and the top of the lateral border of the iliac crest during minimal respiration [11] .

Therapeutic procedures

Procedures of Tripollar Radiofrequency Application: Patient was placed into a comfortable supine lying position. The treated area covered by glycerol oil. The treatment was applied 2 days per week for 10 sessions. Apply tripollar RF using the head on spot fat areas, the applicator was employed with slight pressure in a continuous sweeping movement over the skin. Treatment duration was 40 minutes in each session [12].

Procedures of Ultrasound Cavitation

The session protocol was performed under the following methods: 1. The patients should drink some water before the treatment. 2. Clean the skin with alcohol cotton. 3. Application of conductive gel on the area to be treated. 4. Application treatment of ultrasound cavitation for approximately 20 minutes on each side of abdomen. 5. Cavitation frequency will be 40 KHz. 6. Treatment was applied 2 times per week for 10 sessions [13,14].

Statistical analysis: All statistical analyses were carried out by using the statistical package for the social sciences (SPSS, version 19 for windows; SPSS Inc., Chicago, Illinois, USA).The Kolmogorov–Smimov test was used to check the normality of the data. Descriptive statistics were used for comparison of the mean age, height, weight, and body mass index. Multivariate Analysis of Variance (MANOVA) test was used to show the difference in difference between pre and post treatment result among three groups (A, B and C).The level of significance for all statistical tests was $\leq$ 0.05. A preliminary statistical power analysis determined that a sample size of 30 for this study was adequate to achieve more than 80% power and significant level was $\leq$ 0.05.

RESULTS

Subject characteristics: A comparison of the demographic data of 30 participants in three groups revealed no significant differences between the three groups as regards to mean age, height, weight, body mass index (Table 1).

Table 1: Demographic data of patients for groups (A, B and C).

Variables	Group A	Group B	Group C	F-value	P-value	Level of significant
Age (years)	38.7±6.63	34.3±7.76	35.4±8.89	0.858	0.435	N.S
Weight (kg)	77.97±5.07	85.74±2.41	84.95±10.52	3.643	0.05	N.S
Height (m)	2.05 ± 1.58	1.9 ± 161.5	2.8 ± 160.4	2.282	0.115	N.S
BMI (kg/m2)	33.55±1.31	33.57±1.57	32.99±3.73	0.179	0.837	N.S

*Significant at alpha level <0.05
SD = standard deviation M = meter P = probability
BMI = Body Mass Index NS = non significance
KG = kilogram SIG = significance

Within Group's Comparison for Waist Circumference and Ultrasonographic Measurement Pre and Post Treatment

Group A: As presented in table (2), within group's comparison, Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of WC at post treatment in compare to pretreatment (P-value =0.002*). As well there was significant reduction of US measurements of abdominal

subcutaneous fat thickness at post treatment in compare to pretreatment (P-value =0.0001*).

Table 2: The waist circumference and ultrasonographic measurement pre and post treatment in group (A).

	Time of measurement		MD	% of improvement	P- value	Sig
	Pre treatment Means ± SD	Post treatment Means ± SD				
WC	±107.2211.67	95.88 ±8.43	11.33	10.57%	0.002*	S
US Measurements	2.58±0.24	1.9±0.49	0.68	26.35%	0.0001*	S

Group B: As presented in table (3), within group's comparison, Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of WC at post treatment in compare to pretreatment (P-value =0.028*). As well, there was significant reduction of US measurements of abdominal subcutaneous fat thickness at post treatment in compare to pretreatment (P-value =0. 01*).

Table 3: The waist circumference and ultrasonographic measurement pre and post treatment in group (B).

	Time of measurement		MD	% of improvement	P- value	Sig
	Pre treatment Means ± SD	Post treatment Means ± SD				
WC	±113.334.12	105.66 ±5.59	7.66	6.76%	0.028*	S
US measurements	2.45±0.18	2.14±0.27	0.31	12.65%	0.01*	S

Group C: As presented in table (3), within group's comparison, Multiple pairwise comparison tests (Post hoc tests) revealed that there was significant reduction of WC at post treatment in compare to pretreatment (P-value =0.0001*). As well, there was significant reduction of US measurements of abdominal subcutaneous fat thickness at post treatment in compare to pretreatment (P-value =0.0001*).

Table 4: The waist circumference and ultrasonographic measurement pre and post treatment in group (C).

	Time of measurement		MD	% of improvement	P- value	Sig
	Pre treatment Means ± SD	Post treatment Means ± SD				
WC	105.44 ±4.74	89.55 ±13.62	15.88	15.07%	0.0001*	S
US measurements	2.38±0.48	1.71±0.31	0.67	28.15%	0.0001*	S

Between Groups Comparison for Waist Circumference and Ultrasonographic Measurement for the Three Groups Pre and Post treatment

Waist Circumference: Multiple pairwise comparison tests (Post hoc tests) revealed that, there was no significant difference of the mean values of the "post" treatment among (group A versus C), and (group A versus B) with (P=0.549, and P=0.134) respectively, while there was a significant difference between (group B versus C) with (P=0.006). Additionally, there was no statistical significant difference between group A and group C. Also, there was no statistical significant difference between group A and group B, while there was a statistical significant difference between group B and group C.

Table 5: Bonferroni multiple comparison tests (Post hoc tests) of Waist Circumference for three groups pre and post treatment.

Waist circumference		Mean difference	P-value	Sig
Pre treatment	Group (A) Vs. Group (B)	-6.11	0.31	NS
	Group (A) Vs. Group (C)	1.77	1	NS
	Group (B) Vs. Group (C)	-7.88	0.166	NS
Post treatment	Group (A) Vs. Group (B)	-9.77	0.134	NS
	Group (A) Vs. Group (C)	6.33	0.549	NS
	Group (B) Vs. Group (C)	-16.11	*0.006	S

Multiple pairwise comparisons between pre and post treatment values for waist circumference at different groups.

Pre Vs. post	Group A	Group B	Group C
p-value	*0.002	*0.028	*0.0001

Ultrasonographic Measurement: Multiple pairwise comparison tests (Post hoc tests) revealed that, there was no significant difference of the mean values of the "post" treatment among (group A versus B), and (group A versus C) with (P=0.182, and 0.317) respectively, while there was a significant difference between (group B versus C) with (P=0.027). Additionally, there was no statistical significant difference between group A and group C. Also, there was no statistical significant difference between group A and group B, while there was a statistical significant difference between group B and group C.

Table 6: Bonferroni multiple comparison tests (Post hoc tests) of US Measurements of Abdominal Subcutaneous Fat Thickness for three groups pre and post treatment.

Ultrasonography		Mean difference	P-value	Sig
Pre treatment	Group (A) Vs. Group (B)	0.13	0.39	NS
	Group (A) Vs. Group (C)	0.2	0.212	NS
	Group (B) Vs. Group (C)	0.06	0.669	NS
Post treatment	Group (A) Vs. Group (B)	-0.24	0.182	NS
	Group (A) Vs. Group (C)	0.18	0.317	NS
	Group (B) Vs. Group (C)	0.43	*0.027	S

Multiple pairwise comparisons between pre and post treatment values for ultrasonography at different groups.

Pre Vs. post	Group A	Group B	Group C
p-value	*0.0001	*0.01	*0.0001

DISCUSSION

Abdominal obesity, also known as beer belly, beer gut, pot belly or clinically as central obesity, is when excessive abdominal fat around the stomach and abdomen has built up to the extent that it is likely to have a negative impact on health. There is a strong correlation between central obesity and cardiovascular disease [15].

This study was conducted to investigate and compare the effect of tripollar RF lipolysis, US cavitation and their combination (US cavitation and tripollar RF) on subcutaneous fat thickness and WC in patients with abdominal adiposity.

There was statistical significant difference between pre and post treatment within each group (A, B and C) for abdominal subcutaneous fat thickness and WC. But there was no statistical significant difference among (group A and group C) and (group A and group B); while there was a statistical significant difference between (group B and group C).

Regarding US cavitation in group (A), the results revealed significant improvement in all measured parameters, but less than group (C) (combination therapy), and more than group (B) (tripollar RF) with $p< 0.05$.

In an attempt to confirm the previous results, It was reported that, treatment of localized adiposity with unstable cavitation which termed ultra sound cavitation, producing the opening of the interstitial liquid triglycerides. The damage occurring to adipocytes results in an inflammatory response composed primarily of macrophages, neutrophils, and plasma cells attracted to engulf and transport the damaged cells lymphocytes [16].

Another study used ultrasound cavitation in order to stimulate the metabolic activity in subcutaneous adipose tissue in order to evaluate the effectiveness of this technique in increasing the strength of the connective tissue and decreasing subcutaneous fat thickness. There was an increase in cell permeability in the short term, which stimulated the exchange of substances of fat cells and the activation of enzymes that break down fat. The protective and therapeutic effects of acoustic waves are complex and include stimulation of lipolysis, the release of toxic aldehyde products of lipid oxidation, reduction of oxidative stress, reinforcement of antioxidants, a better synthesis of collagen and measurable and visible improvement skin condition. This improves the skin condition was clearly observed by the final evaluation. This was confirmed by ultrasound examination which showed increased density and firmness of the collagen elastic fibers in the dermis and decrease in local subcutaneous fat tissue [17].

Regarding tripollar RF treatment in group (B), the results revealed significant improvement in all measured parameters in the current group but less than group (A and C) with $p< 0.05$. These results were confirmed by Donofrio [19] reported that one of the newest fat reduction technologies is radiofrequency, which delivers energy to the areas of fat by driving controlled heat deep within the fat cells and subsequently destroys them. It is being widely used by dermatologists with much success for people with pockets of excess fat. Since there is no downtime with this procedure, patients can resume their regular activities immediately. Furthermore, the author reported that radio frequency is a very versatile procedure that can be used on any area of the body, from large areas like the abdomen to very small areas such as the chin with the same degree of success. People who are not considered overweight but have stubborn pockets of unwanted fat that are not responding to diet and exercise, radio frequency is a good. Another benefit of radio frequency is its ability to both reduce fat and tighten the skin by directing energy to target collagen. For example, a patient with flabby upper arms may have more loose skin than fat in this area. In this instance, it might use radiofrequency to tighten the skin first and then remove excess fat.

Also, Goldberg et al. [20] demonstrated that tripollar RF alone is technology that provided beneficial effects on the reduction of abdomen

and thigh circumferences and an overall improvement in the appearance of cellulite.

Regarding combination therapy in group (C) the results revealed significant improvement in all measured parameters more than both groups (A and B) with $p< 0.05$.

Our findings matched with Teitelbaum and his colleagues (2007) who found a significant effect on circumference reduction and body contouring by US cavitation when combined with tripollar RF. Significant circumference reduction effect may indicate a 50% greater mean circumference reduction than was achieved by a single treatment session of either treatment alone [21].

Also, Coldiron (2008) reported several explanations for the increased efficacy of the combined US and RF modalities. While the disruption of adipocytes is achieved only by the US cavitation, the application of RF treatment may increase its effect and the free fat clearance from the treated area. However the combination of therapies does not add up to a thermal injury to adjacent tissues such as blood vessels, nerves or skin [22].

CONCLUSION

It is clear that US cavitation, tripollar RF and their combination could be utilize for management of abdominal adiposity, but the combination of US cavitation and tripollar RF lipolysis or US cavitation only more effective than tripollar RF lipolysis in reduction of WC and subcutaneous fat thickness in management of abdominal adiposity.

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Conflicts of interest: None

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