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Low level laser versus ultra-sound cavitation on fat thickness layer of abdominal region

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Abstract: *Background: Obesity is a condition of abnormal excessive fat accumulation in adipose tissue. Abnormal blood lipids associated with obesity have been firmly established as a risk factor for the development of cardiovascular diseases. Purpose: This study was conducted to compare the effectiveness of low level laser therapy versus ultra-sound Cavitation on fat thickness layer of abdominal region measured by ultra-sonography. Methods: Forty patients aged from 25-35 years and BMI (25-29.9) were assigned randomly into 2 equal groups: Group (A) received ultra-sound cavitation. Group (B) received low level laser therapy (632.8nm-16J/cm2). The modalities were applied for 30 min, twice weekly for 12 weeks in both groups. Both groups received the same diet program throughout the treatment period. Assessment was carried out for body weight using weight scale, waist/hip ration using stretch resistant tape and fat thickness layer of abdominal region using ultra-sonography before and after treatment. Results: showed that there was a significant reduction of body weight, waist/hip ratio and abdominal fat thickness below the umbilicus after treatment in both groups and a significant reduction of abdominal fat thickness above umbilicus group A only. Comparison between post treatment values of waist/hip ratio and abdominal fat thickness above and below the umbilicus showed significant difference between both groups with favorable results for group A. Conclusion: Low level laser therapy (LLLT) and ultrasound cavitation are effective physical therapy modalities in treatment of abdominal obesity by reducing body weight, waist/hip ratio and abdominal fat thickness.*

Keywords: *Low level laser therapy, ultra-sound cavitation, abdominal obesity, fat thickness layer, ultra-sonography of fat thickness.*

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I. Introduction

Obesity is the most common metabolic disorder in human and an increasingly significant health problem. There are many etiological causes for obesity. Excess fat accumulation caused by imbalance between energy intake and expenditure [1].

Abdominal obesity is known as belly fat or clinically as central obesity as there is accumulation of abdominal fat resulting in an increase in waist size. There is a strong correlation between central obesity and cardiovascular disease [2, 3].

New techniques are demanded in body aesthetic medicine for noninvasive procedures which motivates the researchers to develop a replacement techniques for the traditional treatments for body contouring. In the past, liposuction or other surgical procedures are the only way to achieve dramatic improvement in body through removing local fat deposits. The causes of drawbacks of these surgical approaches are patient related (hospitalization, general or tumescent anesthesia, pain, post-operative bruising and swelling, long post operative recovery, and other risks inherent to surgical procedures) and surgeon related (create technical challenges for surgeons) [4].

Low level laser therapy ((LLLT)) or ultrasound cavitation show a safe and effective noninvasive technology for body contouring and removal of unwanted body fat. This facet is confirmed by multicenter and clinical trials assessing the safety and efficacy of a focused therapeutic ultrasound device and LLLT for noninvasive body contouring [5].

The present study was designed to compare between the effect of Low Level laser Therapy (LLLT) and the effect of ultra-sound cavitation on fat thickness layer of abdominal region and waist hip ratio in abdominal obese patients.

II. Materials and methods

A. Participants

A statistical power analysis suggested that sample size above 15 participants per group were required to achieve more than 80% power. Forty patients of both genders (30 female and 20 male) with body mass index ranged from 25 to 29.9 kg /m2, their ages ranged from 25 to 35 years with mean age (30.31±1.57 years) were recruited from Sohag University Hospital in the period between Oct 2016 and Feb 2017. Each patient signed a consent form appendix (I). They were assigned to two groups randomly.

Group A: received ultrasound cavitation for 30 minutes on abdomen two times per week, for 12 weeks with continuous emission and frequency of 40 KHz, 3-6 W/cm2, 60W with 10cm2 active surface [6].

Group B: received LLLT with wavelength 632.8 nm for 30 minutes on abdomen two times per week, for 12 weeks [7].

The patients were included in the study if their age between 25 to 35 years old, BMI ranged from 25 to 29.9 kg /m2 and patients were indicated for body contouring in the waist and hips with west circumference greater than 97.5 cm for men and 92.3 cm for women [8]. Patients also should not participate in any form of regular physical activity or any dietary program before the study.

Patients were excluded from this study if they had severe hypo or hyper tension, photosensitivity body mass index more than 35 or less than 30, diabetes cardiovascular instability, renal and hepatic disorders, medical, physical, or other contraindication for body sculpting -weight loss, current use of medication known to affect weight levels and or to cause swelling diagnosis of and / or talking medication of irritable bowel syndrome active infection, wound, or other external trauma to the areas treated with laser or ultasound cavitation or pregnant, breast feeding, or planning pregnancy female patients.

B. Study design and randomization

The study was designed as a prospective randomized clinical trial in which patients were assigned randomly into two groups. Randomization was used to eliminate the researches' bias and was carried out by a blinded and an independent research assistant who opened sealed envelopes that contained a computer generated randomization card.

C. Instrumentations

Standard weight scale, was used to measure weight and height and body mass index (BMI) then calculated for each patient.

1) Weight measurement procedures

For the measurement of weight, the patient was asked to step up backwards onto the scale and stand still over the center of the scale with body weight evenly distributed between both feet backward facing away from the readout of the weight. The patient's arms were hanging freely by the sides of the body, with palms facing the thighs. The patient should hold his/her head up, and face forward. Weight was recorded to the nearest 0.5 kg using the recommended scale with a digital readout.

2) Height measurement procedures

For the measurement of standing height, the patient was asked to stand with his/her back against the board. The back, scapulae and buttocks were in contact with the vertical height measuring board if possible, or whichever part of the body touches the board first. The weight of the patient was evenly distributed on both feet. The patient was asked to place the legs together, bringing the ankles or knees together, whichever comes together first. The moveable headpiece was brought onto the upper most (superior) point on the head with sufficient pressure to compress the hair. The measurement was recorded to the nearest 0.1cm.

3) BMI calculation

The patient BMI was calculated according to the following equation:

MBI=(Weight (in kg))/(〖Height〗^2 (in m)) [9].

4) Waist to hip ratio Measurement procedures

Waist and hip circumference was measured by the standard stretch resistant tape measurement that provides a constant 100 g tension. The waist circumference was measured at amid point between the lower margin of last palpable rip and the top of the iliac crest.

Hip circumference was measured around widest portion of the buttocks, with the tape parallel to the floor.

For both measurements , the individual should stand with feet close together, arms at the side and body weight evenly distributed, and should wear little clothing. The subject should be relaxed, and measurements should be taken at end of expiration. Each measurement should be repeated twice; if measurements were within

1 cm from one another, the average should be calculated. If the difference between two measurements exceeds 1 cm the two measurements should be repeated.
It is calculated by dividing the measurement of the waist by the measurement of the hips.

5) Ultra sonography assessment procedures of fat thickness

Investigation medical ultrasound have been used to evaluate the thickness of the abdominal fat layer at the affected area in relation to a fixed point for every measurement. Measurement was carried out by the same investigator. With the patient in relaxed supine lying poison the area to be investigated was uncovered and the gel was applied over it. Measurement of fat thickness above and below the umbilicus were recorded (around umbilicus by 5 cm). The scan was obtained and transferred to the monitor screen.

D. Treatment procedures

Both groups (A and B) received the same diet program throughout the treatment period.

1) Ultrasound cavitation procedures,

Patients received ultrasound cavitation (model h-1000 made in Korea) for 30 minutes on abdomen with continuous emission and frequency of 40 KHz, 3-6 W/cm2, 60W with 10cm2 active surface, 2 times/ week with 3 days apart for 12 weeks. Patient was in supine lying position. The time of treatment was adjusted (for 30 min) then start treatment. Abundant amount of ultrasound gel as a medium for delivering ultrasound cavitation was applied to the abdominal area. The entire surface of the transducer probe should be kept in contact with the skin of abdomen all the time by moving in a circular motion then the treatment head of ultrasound was moved. Move the sound head at approximately 4 cm/sec, with an overlap one-half the width of the sound head. At the end of treatment ultrasonic unit was cleaned [6].

2) Low level laser therapy application

Patient received low level laser therapy (model h-1000 made in Korea) with wave length of 632 nm, 2 times/ week with 3 days apart for 12 weeks. The patient position was lying comfortably flat on his/her back.

The patient was fitted with blind folds. The laser 6 sheets was applied 2 cm apart on abdomen for 30mins. The total laser energy that was received approximately 6.6 J/cm2. Patient and therapist wore protective glasses [7].

E. Statistical analysis

Data were collected before initiation of the treatment (pre treatment), and after 12 weeks of treatment (post treatment). Statistical analysis was conducted using SPSS for windows, version 18 (SPSS, Inc., Chicago, IL).

The collected data were analyzed statistically by the descriptive statistics, based on the raw data, where mean and standard deviation of age, height, weight, BMI, fat thickness layer and waist hip ratio variables were calculated for all patients. Inferential statisticial analysis and comparison of weight, fat thickness layer and waist hip ratio were made by 2x2 mixed design MANOVA at pre and post-treatment periods with group A and group B. Bonferroni post-hoc test was used to reveal the differences and to detect the statistical significance level of progression or regression (comparison) within group (compare between pre and post treatment in each group) and between groups (compare between the two groups, pre treatment and post treatment). Independent t-test was used for comparison between groups age (years), weight (Kg), height (cm) and BMI (kg/m2) variables. The level of significance was set at the 0.05 level [10].

III. Results

F. Baseline and demographic data

There were no statistically significant differences (P>0.05) between subjects in both groups concerning age, body mass, height, and BMI (Table 1).

G. Body weight:

As presented in table (2), within group's comparison the mean values of body weight in the "pre" and "post" tests revealed that there was significant reduction of body weight at post treatment in comparison to pre treatment in both groups A and B with P-value<0.001. Between groups comparison for mean values of body weight showed no significant differences pre treatment with (P=0.172) and no significant difference post treatment with (p=0.306) between both groups.

H. Waist/hip ratio:

As presented in table (2), within group's comparison the mean values of Waist/hip ratio in the "pre" and "post" tests revealed that there was significant reduction Waist/hip ratio at post treatment in compare to pre treatment in both groups A and B with P-value<0.001. Between groups comparison for mean values of

Waist/hip ratio showed no significant differences pre treatment with (P-value=0.063) but there was significant difference post treatment with (P-value=0.035) and this significant reduction in favor to group A than group B.

I. Fat thickness above umbilicus:

As presented in table (2), within group's comparison the mean values of fat thickness above umbilicus in the "pre" and "post" tests revealed that there was significant reduction fat thickness above umbilicus at post treatment in compare to pre treatment in group A with P-value<0.001 but there was no significant difference in the post treatment values of Group B in compare to pre treatment values with P-value =0.081. Between groups comparison for mean values of fat thickness above umbilicus showed no significant differences pre treatment with (P-value =0.101) but there was significant difference post treatment with (P-value =0.009) and this significant reduction in favor to group A than group B.

J. Fat thickness below umbilicus:

As presented in table (2), within group's comparison the mean values of fat thickness below umbilicus in the "pre" and "post" tests revealed that there was significant reduction fat thickness below umbilicus at post treatment in compare to pre treatment in both groups A and B with P-value<0.001. Between groups comparison for mean values of fat thickness below umbilicus showed no significant differences pre treatment with (P-value =0.062) but there was significant difference post treatment with (P-value =0.004) and this significant reduction in favor to group A than group B.

IV. FIGURES AND TABLES

Table 1: General characteristics of the two studied groups

Items	Group A	Group B	Comparison		S
	Mean ± SD	Mean ± SD	t-value	P-value	
Age (yrs)	29.2±2.95	31.42±3.54	-1.843	0.076	NS
Body mass (Kg)	86.03±12.59	92.57±10.78	-0.21	0.835	NS
Height (m)	1.75±0.15	1.81±0.1	-1.25	0.222	NS
BMI (Kg/m2)	27.85±1.46	27.96±1.4	-1.496	0.146	NS

Data are expressed as mean ± SD.
NS= p> 0.05= not significant.
*Significant level with alpha level<0.05, SD: standard deviation, t-value: calculated t,
p-value: probability value, Kg.: Kilogram, cm: centimeter, kg/m^2: Kilogram per meter square.

Table (2): Descriptive statistics and multiple pairwise comparison tests (Post hoc tests) for the body weight (Kg), Waist hip ratio (%), Fat thickness above umbilicus and Fat thickness below umbilicus in pre and post treatment for both groups.

Dependent variables		Pre treatment	Post treatment	MD	% of change	p- value
		Mean± SD	Mean± SD			
Body weight (Kg)	Group A	86.03±12.59	77.53±10.78	8.5	9.88	0.0001*
	Group B	92.00±10.62	81.36±9.27	10.63	11.55	0.0001*
	MD	-5.96	-3.83			
	p- value	0.172	0.306			
Waist hip ratio (%)	Group A	0.95±0.10	0.91±0.09	0.043	4.52	0.0001*
	Group B	1.04±0.12	1.00±0.12	0.036	3.46	0.0001*
	MD	-0.082	-0.09			
	p- value	0.063	0.035*			
Fat thickness above umbilicus	Group A	34.28±9.61	20.47±6.83	13.80	40.25	0.0001*
	Group B	29.12±6.79	27.35±6.47	1.77	6.07	0.081
	MD	5.15	-6.88			
	p- value	0.101	0.009*			
Fat thickness below umbilicus	Group A	31.04±5.63	20.55±5.17	10.49	33.79	0.0001*
	Group B	27.71±3.51	25.5±3.26	2.207	7.93	0.005*
	MD	3.33	-4.95			
	p- value	0.062	0.004*			

*Significant level is set at alpha level <0.05
SD: standard deviation MD: Mean difference P-value: probability value

V. DISCUSSION

The present study was designed to the present study to compare between the effect of (LLLT) and the effect of ultra-sound cavitation on fat thickness layer of abdominal region and waist hip ratio in abdominal obese patients.

Obesity is an increasingly significant health problem [1]. The study was carried out on 40 abdominal obese patients who were assigned to two groups randomly:

Group A, which received ultrasound cavitation for 30 minutes on abdomen two times per week, for 12 weeks and group B received LLLT with wavelength 632.8 nm for 30 minutes on abdomen 2 times per week, for 12 weeks. Regarding the results of body weight, there was statistically significant decrease of body weight in both groups A and B with percentage of improvement (9.88 % and 11.55 %) respectively with statistically non-significant difference between both groups A and B after treatment application. Regarding the results of waist/hip ratio, there was statistically significant decrease of waist/hip ratio in both groups A and B with percentage of improvement (4.52 % and 3.46%) respectively with statistically significant better improvement in group A after treatment application. Regarding the results of fat thickness above umbilicus, there was statistically significant decrease of fat thickness above umbilicus in both groups A and B with percentage of improvement (40.25 % and 6.07%) respectively with statistically significant better improvement in group A after treatment application. Regarding the results of fat thickness below umbilicus, there was statistically significant decrease of fat thickness above umbilicus in both groups A and B with percentage of improvement (33.79 % and 7.93%) respectively with statistically significant better improvement in group A after treatment application.

A lot of effort was exerted with each patient to reduce the influence of the possible errors inherent in this study. The limitations of this study were variability in the patient's reaction to the treatment modalities and its effect on the rate of recovery. Also, results may be affected by the psychological condition of the patients at the time of performance (Assessment and Treatment). Some patients refused to complete the study and others don't adhere to the diet and the treatment sessions, both types of those patients were excluded from the results of the study.

The results of ultra-sound cavitation treatment of group (A) can be attributed to mechanism of fat cell destruction through the ultrasound as ultrasound produces bubble in the tissue where the fat cells are found, the bubble expands and then it is immediately compresses, then temperature increases due to the pressure, sudden variation and the bubble explodes [11].

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 [12].

Unleashing the destruction of adipose fat deposits the fat contained (triglycerides) fragments into di - glycerides is dispersed into the interstitial fluid among the cells and then cleared via the lymphatic system and transported through the vascular system to the liver. Phagocytosis of released lipids and cellular debris occurrs after 14 to 28 days. Phagocytized lipids undergo normal hepatic metabolism where, fat metabolized by the lipase enzyme into glycerol and free fatty acids, Glycerol is phosphorylated and transported through the vascular system [13].

These results are consistented with the results of Mohamed [14] in their published study to compare between cavitation with radiofrequency and mesotherapy on abdominal adiposity. Body weight, height, waist hip ratio and skin fold were measured before and after intervention. Results showed a significant improvement in the three groups in waist circumference, waist hip ratio, and suprailiac skin fold in favor of cavitation radiofrequency group, with no significant difference in body weight and BMI in the three groups after intervention.

The result of this study came in accordance with Shek [15] who reported a study of 12 healthy men and women with BMIs not more than 30 kg/m2 and SAT ≥2.5 cm at the treatment site, whose anterior abdomens were treated with an average of 161 J/cm2. At 12 weeks there was an average decrease in waist circumference of 2.1 cm. Higher fluence was significantly correlated with a greater decrease in waist circumference.

The result of this study also came in accordance with a similar study conducted by Shalom [16] who evaluated the safety, tolerability, and histologic outcome of lipolysis using a novel device in human subjects on six healthy adults with an average BMI of 25.5 kg/m2 and an SAT ≥1.2 cm at the treatment site. The patients had one side of their abdomen treated with High Intensity Focused Ultra Sound (HIFU) and the other side with placebo. There was no statistically significant increase in lipids, liver enzymes, or clinical chemistry after the procedure. During abdominoplasty, treated skin was sent for histopathology, which showed fat necrosis with infiltration of lymphocytes and macrophages without adjacent tissue damage.

Furthermore, our results corroborate those from Jewell [17] who performed a sham-controlled, randomized trial to evaluate the safety, tolerability, and effectiveness of HIFU for body contouring. The patients were randomly assigned to treatment of their anterior abdomen and flanks with three passes of 47 J/cm2 (141 J/cm2 total), 59 J/cm2 (177 J/cm2 total), or 0 J/cm2 (0 J/cm2 total). Patients who received 141 J/cm2 showed an average reduction in waist circumference of 2.1 cm 12 weeks after treatment. Patients treated with 177 J/cm2 had an average reduction of 2.52 cm while those in the control group averaged a 1.21 cm reduction with no severe adverse events were reported.

The results of the current study are in consistence with Solish [18] who studied the effects of different fluences on fat reduction using HIFU in a randomized, single-blinded postmarketing study. Forty-seven patients had their anterior abdomens treated with three passes of 47 J/cm2, 52 J/cm2, or 59 J/cm2 for a total of 141 J/cm2, 156, J/cm2, or 177 J/cm2, respectively. At the 1-week follow-up visit, there was an average abdominal circumference reduction of 2.51 cm, with no statistically significant difference between the different fluences and the amount of reduction in circumference.

Our results corroborate those from Gadsden et al., [13] in their clinical trial investigated the safety of this HIFU device in human patients. Results confirmed that the HIFU effects were limited to targeted SAT layers. Histopathology revealed well-demarcated disruption of adipocytes within the targeted SAT. There were no changes in clinical laboratory parameters, and no serious device-related adverse events occurred. Optimal clinical outcomes were achieved with lower energy levels, which provided beneficial effects with the least amount of discomfort.

Also the result of this study came in agreement with Palumbo [19] who studied the effects of a new low frequency high intensity Ultra sound technology both transcutaneous and surgical on human adipose tissue, ex vivo study, showed that, US exposure caused a significant weight loss and fat release. Evaluation of histological characteristics of US-irradiated samples showed a clear alteration of adipose tissue architecture as well as a prominent destruction of collagen fibers which were dependent on US intensity and most relevant in saline buffer-infiltrated samples. The analysis of the composition of lipids in the fat released from adipose tissue after US treatment with surgical device showed a significant increase mainly of triglycerides and cholesterol. US exposure had been shown to induce apoptosis as shown by the appearance of DNA fragmentation.

The result of this study came in agreement with Jewell [20] who reviewed the published literature and suggested that noninvasive body-sculpting techniques such as radiofrequency ablation, cryolipolysis, external low-level lasers, laser ablation, nonthermal ultrasound, and HIFU may be appropriate options for non-obese patients requiring modest reduction of adipose tissue. However, HIFU is the only treatment that can produce significant results in a single treatment. Early clinical data on HIFU supported its efficacy and safety for body sculpting. In contrast, radiofrequency, laser therapy, and injection lipolysis have been associated with significant risks of adverse events.

The results of the study were in agreement with Ascher [21] who evaluated the clinical safety and efficacy of the Contour I system (a noninvasive fat reduction device produces nonthermal pulsed ultrasonic waves) when the intervals between treatments are shortened on twenty-five healthy Caucasian women were selected from the patient population at two clinics in Paris, France, and received three 30- to 90-minute Contour I treatments in the abdominal region at two-week intervals. Results showed that successive Contour I treatments at two-week intervals were safe and tolerable and also significantly reduced treatment area circumference.

Furthermore, Our results corroborate those from Fatemi and Kane [22] who published a retrospective review of 85 healthy men and women with BMIs <30 kg/m2 and an subcutaneous adipose tissue (SAT) ≥2.1 cm at each treatment site treated with a mean energy level of 134.8 J/cm2 over two passes on their anterior abdomen and flanks. The mean decrease in waist circumference was 4.6 cm after 3 months. Serum cholesterol, triglycerides, high- and low-density lipoproteins, and liver enzymes were measured in ten patients for 16 weeks after the procedure without any statistically significant changes.

The results of the current study are in agreement with Brown [23] who studied the physics of focused external ultrasound using the and attempted to validate its efficacy in a porcine model. Gross and histologic evaluations of porcine adipose tissue after treatment with the device con-firmed cavitation induced zones of injury in the adipose tissue with sparing of nervous and vascular structures as well as skin.

Also the result of this study came in agreement with the study of Sabbour and El-Banna [6] that was conducted to determine the efficiency of cavitation ultrasound therapy in reducing visceral adiposity in fifty perimenopausal obese women with BMI between 31.5 and 40.04Kg/ m2, WHR between 0.9 and 0.95% and waist circumference between 89 and 108 cm. Group A followed low-calorie diet alone. While, group B received cavitation ultrasound therapy on the abdomen region and followed a low-calorie diet. The results of this study testified that the combination of cavitation ultrasound therapy and low-calorie diet characterized by a higher efficiency than a low-calorie diet alone in lowering anthropometric, total body composition and plasma liopoprotein variables.

Furthermore, our results corroborate those from Moreno-Moraga [24] who conducted a study was to assess the efficacy and safety of a novel non-invasive focused ultrasound system on 30 patients. Each patient underwent three treatments at 1-month intervals. Areas treated were the abdomen, inner and outer thighs, flanks, inner knees, and male breasts. Ultrasound measurements and circumference measurements were used to assess changes in fat thickness. This study showed the efficacy and safety of focused ultrasound as a non-invasive transdermal method for reducing unwanted fat deposits in the body.

Our results are consistent with a study carried out by Murray et al., [12] to document the feasibility of use and mechanism of action of high intensity focused ultrasound (HIFU) for adipose tissue removal and non –

invasive body sculpting. The use and mechanism of action of HIFU therapy for fat removal has been proven in both pre-clinical and human clinical trials and provides a non- invasive method for body sculpting.

On the other hand, our results are in contradiction with Shek [25] who investigated the safety and efficacy of this focused ultrasound device in body contouring in Asians on 53 patients. The overall satisfaction amongst subjects was poor. Objective measurements by ultrasound, abdominal circumference, and caliper did not show significant difference after treatment. There was a negative correlation between the abdominal fat thickness and number of shots per treatment session. Such observation is likely due to smaller body figures. Design modifications can overcome this problem and in doing so, improve clinical outcome.

In our study, the results obtained in of group (B) may be attributed to action of LLLT. The mechanism of action of LLLT on fat remains somewhat controversial. LLLT appears to increase cyclic adenosine monophosphate (cAMP) production via cytochrome C oxidase activation, increased cAMP could activate protein kinase which could stimulate cytoplasmic lipase, an enzyme that converts triglycerides into fatty acids and glycerol, where both can pass through pores formed in the cell membrane causing a shrinkage in adipocytes [26].

The low-level laser energy affected the adipose cell by causing a tran-sitory pore in the cell membrane to open, which permitted the fat content to go from inside to outside the cell [27].

Another possible mechanism of action for release of lipids was proposed to be through activation of the complement cascade which could cause induction of adipocyte apoptosis and subsequent release of lipids [7].

The results of LLLT in our study are consistent with the results of Elkablawy [28] who investigated the effect of the ultrasonic cavitation versus low level laser therapy in the treatment of abdominal adiposity in female post gastric bypass on sixty female suffering from localized fat deposits at the abdomen area after gastric bypass. Results showed a statistically significant decrease in waist circumferences, skin fold and ultrasonography measurements using either low level laser therapy or ultrasonic cavitation after gastric bypass in female.

The results of the study were in agreement with McRae and Boris [29] who performed an independent, physician-led trial to evaluate the utility of LLLT-635 nm for non-invasive body contouring of the waist, hips, and thighs on eighty-six participants. A multi-head laser device was administered every-other day for 2 weeks. Compared with baseline, a statistically significant 2.99 in. (7.59 cm) mean loss was observed at the post-procedure evaluation point. These data further validate the clinical efficacy and safety of LLLT at 635 nm.

Also, the results were confirmed by Avci et al., [26] who reported that low level laser therapy has a potential to be used in fat and cellulite reduction as well as in improvement of blood lipid profile without any significant side effects. One of the main proposed mechanism of actions is based upon production of transient pores in adipocytes, allowing lipids to leak out. Another is through activation of the complement cascade which could cause induction of adipocyte apoptosis and subsequent release of lipids.

The results of this study confirmed the observations of Nestor [30] who assessed the safety and efficacy of low-level laser therapy as a noninvasive method for reducing upper arm circumference in a randomized, double-blind study whereby 20 healthy subjects with a body mass index of 20 to 35kg/m2 received three 20-minute low-level laser therapy or sham treatments (another 20 subjects) each week for two weeks. Laser therapy group showed a combined reduction in arm circumference of 3.7cm versus 0.2cm in the sham treatment after six treatments. The study concluded that, noninvasive low-level laser therapy is safe, painless, and effective in reducing upper arm circumference and is associated with a high degree of subject satisfaction.

Furthermore, the result of this study came in agreement with Caruso-Davis et al., [7] investigated the effect of low level laser therapy on reducing the waist circumference measurements and photographs appearance in 40 subjects with BMI <30 kg/m2. Results confirmed that LLLT gives significant girth loss that is maintained over repeated treatments and is cumulative over 4 weeks of 8 treatments. This girth loss of approximately one inch from the waist was accompanied by a clinically and statistically significant improvement in appearance.

The result of the current study came in accordance with Mulholland [31] in his placebo-controlled, randomized, double-blind, multicentered clinical study that was conducted to evaluate the efficacy of the LLLT using Zerona device for noninvasive body slimming. Comparison of the 2 independent-group mean of change in total combined circumference (total number of inches) from study baseline to end point demonstrated a statistically significant reduction in the circumference measurements between groups by 3 inches or greater reduction in the circumference measurements after 2weeks of treatment in the test group.

The result of this study came in accordance with similar study conducted by Jackson [32] who evaluated the application of a 635nm and 17.5mW exit power per multiple diode laser for the application of non-invasive body contouring of the waist, hips, and thighs in sixty-seven volunteers between the ages of 18–65 with a body mass index (BMI) between 25 and 30 kg/m2. Participants in the treatment group demonstrated an overall reduction in total circumference across all three sites of 3.51 in. Test group participants demonstrated a reduction of 0.98 in. across the waist, 1.05 in. across the hip, and 0.85 in. and 0.65 in. across the right and left thighs from baseline to 2 weeks (end of treatment). So the results of the study suggest that low-level laser therapy can reduce overall circumference measurements of specifically treated regions.

The result of the current study also came in accordance with Neira et al., [27] who investigated the effect of 635-nm, 10-mW diode laser radiation with ex-clusive energy dispersing optics. All microscopic results showed that without laser exposure the normal adipose tissue appeared as a grape-shaped node. After 4 minutes of laser exposure, 80 percent of the fat was released from the adipose cells; at 6 minutes of laser exposure, 99 percent of the fat was released from the adipocyte.

VI. CONCLUSIONS

It can be concluded that, there was greater reduction in body weight, waist/hip ratio and abdominal fat thickness above and below the umbilicus after application of ultrasound cavitation and LLLT with favor for ultrasound cavitation so enhancing the treatment of abdominal obese patients by decreasing body weight, waist/hip ratio and abdominal fat thickness above and below the umbilicus. Also ultrasound cavitation and LLLT were cost effective.

VII. RECOMMENDATIONS

The results of the study had indicated need to consider the following recommendations: Future studies are recommended using other fat reduction modalities such as cryolipolysis. A similar study should be done using LLLT or ultrasound cavitation on other body areas rather than the abdominal area. Follow up studies of various forms of assessment for obesity such as lipid profile. Further studies could be with different intensities of LLLT or cavitation. Future studies are recommended to include patients with different ages. Future studies are recommended to measure potential patient's discomforted during LLLT and Cavitation therapy in abdominal obese patients.

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