

EFFECT OF LOW LEVEL LASER ON ABDOMINAL OBESITY IN WOMEN WITH LUMBER DISC PROLAPSE: A Randomized Controlled Trial

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Abstract:

Background: Obesity is an international health crisis. Low-level laser therapy (LLLT) is a novel, non-invasive procedure for lysing excess fat. This study was designed to evaluate the effect to LLLT on reducing the abdominal obesity in women with lumbar disc prolapse.

Material and methods: Forty women were distributed randomly into two equal groups, group A received an energy restricted diet regime (daily kilocalorie intake restricted to 1200 Kcal/day) and treated by Low Level LASER GaAlAs with wavelength of 680nm and Power 40mw for 20 minutes/ session, two sessions/ week for 8weeks. Group B received the same diet regime for 8 weeks but without application of LASER. Weight, pain score, body mass index, waist circumference and abdominal obesity were measured at baseline then after 8 weeks.

Results: In both groups there was a significant reduction of weight and body mass index post-treatment with $P > 0.05$. Regarding abdominal obesity, waist circumference and pain score percentage results, there was statistically significant difference in favor of group A when compared with group B with $P < 0.05$.

Conclusion: A combined treatment of LLLT and diet may offer a safe and effective treatment modality for obese patients with lumbar disc prolapse.

Keywords: Low level laser, abdominal obesity, Energy restricted diet, lumbar disc prolapse.

Introduction:

Obesity is a health problem of increasing prevalence in every continent and represents a major public health concern ⁽¹⁾. It is associated with numerous co-morbidities such as cardiovascular

diseases (CVD), type 2 diabetes, hypertension, certain cancers, and sleep apnea/sleep-disordered breathing. In fact, obesity is an independent risk factor for CVD ⁽²⁾ and CVD risks have also been documented in obese children ⁽³⁾. Obesity is associated with an increased risk of morbidity and mortality as well as reduced life expectancy ⁽²⁾. Obesity, commonly defined as a body mass index (BMI) of ≥ 30 kg/m² ⁽⁴⁾. It has been reported that the prevalence of obesity in adults is very high in Egypt, particularly among women ⁽⁵⁾.

The prevalence of central obesity among Egyptian adults, according to waist circumference was 24.1%. This percent is relatively high if the association of central obesity with morbidity and mortality is taken into consideration ⁽⁶⁾. The impact of obesity on musculoskeletal and spinal disease, including low back pain, facet arthritis, and degenerative disc disease, has been well documented ⁽⁴⁾.

Because of the impact of obesity on musculoskeletal and spinal disease especially degenerative disc disease has been well documented ⁽⁴⁾ and several studies suggest that high BMI and obesity may be linked to lumbar disc degeneration ⁽⁷⁻¹²⁾. Increased body mass index increases lumbosacral angles, which results in biomechanical changes in the lumbosacral spine resulting in greater flexion of the sacroiliac joints, greater facet degeneration, higher torque on the lumbar discs and joints, and increasing shear forces that may overload the joints ^(13, 14). Sheng et al., proved that obesity predicts spinal diseases in the lower back ⁽¹⁵⁾.

Lasers are devices that amplify or increase the intensity of light to produce a highly directional, high-intensity beam that typically has a very pure frequency or wavelength. They come in sizes ranging from approximately one-tenth the diameter of a human hair to that of a very large building. Lasers produce powers ranging from nano watts to a billion trillion watts (10²¹ W) for very short bursts. They produce wavelengths or frequencies ranging from the microwave region and infrared to the visible, ultraviolet, vacuum ultraviolet, and into the Soft-X-ray spectral regions ⁽¹⁶⁾.

Low level laser therapy (LLLT) is the application of light (usually a low power laser or LED in the range of (1mW – 500mW) to pathology to promote tissue regeneration, reduce inflammation and relieve pain. The light is typically of narrow spectral width in the red or near infrared spectrum (600nm – 1000nm), with a power density (irradiance) between 1mw-5W/cm². It is typically applied to the injury for a minute or so, a few times a week for several weeks. Unlike other medical laser procedures, LLLT is not an ablative or thermal mechanism, but rather a photochemical effect comparable to photosynthesis in plants whereby the light is absorbed and exerts a chemical change ⁽¹⁷⁾.

Material and methods:

Study Design

This study was designed as a prospective, randomized, single-blind, pre–post-test, controlled trial. Ethical approval was obtained from the institutional review board at national institute of laser enhanced sciences, Cairo University [Cu – NILES/ 07/21].

Participants

Forty women complained of low back pain due to the lumbar disc prolapse L4, L5 diagnosed by the orthopedist, age ranged from 30 to 45 years, BMI ≥ 30 kg/m² and they all were medically free from any other disease that may interfere with treatment program. Women were able to follow instructions and they were collected from Tanta university hospital and Tanta sport medicine Hospital and received the treatment protocol in physical therapy department of Tanta sport medicine hospital.

Women took any pain medications, complained of chronic diseases as diabetes mellitus or hypertension, had any types of food allergies, diagnosed as lumbar disc herniation or had any previous surgical interventions in the lumbar vertebrae were excluded from this study.

Randomization

A written informed consent was signed from each participant after explanation the study's nature, purpose and benefits and about the confidentiality of any obtained information. The participants were randomly divided into two groups (study and control), 20 patients in each group.

Interventions

The control group consisted of 20 women received only a restricted diet regime, while the study group consisted of 20 women who received the same diet as well as treated with low level laser GaAlAs for 8 weeks.

The energy restricted diet regime

All women in both groups received the daily kilocalorie diet intake restricted to 1200 Kcal/day. Each woman had given a booklet including a database of the desired foods and micronutrient and its alternatives during the treatment period. The therapist asked each woman to select her foods freely from the booklet and give instructions about planning her meals to help adhere to the prescribed kilocalories and assigned macronutrient. All women were advised to keep 3-day dietary records and interviewed by the therapist once weekly.

The Low Level LASER

Each woman in the study group treated by application of low level laser on abdomen; GaAlAs, wavelength of 680nm and Power 40mw for 20 minutes per session, 2 sessions per week for 8 weeks. The diode laser device used was (Meridian LAPEX BCS pro LASER, Meridian company, Korea and serial number BPB000081). Uniphly protective goggle was worn by patients and therapist during Low Level Laser application.

Outcome Measures

All measures were assessed in both groups at baseline and after 8 weeks.

Pain measurement

Was assessed using the Visual analogue scale by asked each woman to rate her pain on a 1 to 10 scale, where 1= no pain and 10= worst pain

Body fatness measurement

Body weight is interpreted using Body Mass Index (BMI) which is known as the Quetelet index and calculated by dividing each woman weight in kilograms by her height in meters squared ⁽¹⁸⁾. The

World Health Organization (WHO) defined that the overweight as $BMI \geq 25\text{kg/m}^2$ to 29.9kg/m^2 and the obesity as $BMI \geq 30\text{kg/m}^2$ ⁽¹⁹⁾.

Waist circumference measurement

Waist is defined as the smallest circumference of the torso midway between the inferior margin of the 12th rib and the iliac crest in horizontal plane⁽¹⁹⁾, this measurement conducted by Erchon body Tape measure, with the subject stood, feet 25 to 30 cm apart, and weight evenly distributed. The therapist stood by the side of the subject and with a non-stretchable tape applied a snug fit that did not compress soft tissues. WHO identify women with abdominal obesity at waist circumference $\geq 88\text{cm}$ ⁽¹⁹⁾.

Abdominal obesity measurement

Abdominal (android) obesity is a case of obese individual in which the body's extra fat gets distributed over the abdominal region because of which the individual's shape seems to be apple shaped. This measurement carried out by the radiologist measured the fat mass in the abdominal "android" region using Dual energy x-ray absorptiometry (DEXA).

Statistical analysis:

The data regarding to the participant's age, sex, waist circumference and the examined region was collected before and after the treatment program. The data collections were performed at the same sequence and procedures for all participants in the two groups of the study. The data were analyzed statistically to obtain the following statistical tools: Descriptive statistics in form of mean and standard deviation, paired an Unpaired T- test was used to compare the dependent and independent variables in both groups to detect the level of significance. Each hypothesis was tested separately by using the appropriate statistical tools. The data analysis and the level of significance were set at the level of ≤ 0.05 .

RESULTS:

At baseline, the data were not significantly different between both groups regarding age, height, weight, BMI, pain score percentage, waist circumference and abdominal obesity as shown in (table 1).

Within groups:

In the study group (GA), It was found that the mean value of weight was decreased significantly from 112.5 ± 23.25 kg at baseline to 98.45 ± 24.26 kg after 8 weeks post treatment, as $P < 0.05$.

The mean value of BMI was decreased significantly from 43.01 ± 6.438 kg/m^2 at baseline to 37.57 ± 6.970 kg/m^2 after 8 weeks' post-treatment, as $P < 0.05$.

The mean value of abdominal obesity was decreased significantly from $48.08 \pm 6.107\%$ at baseline to $32.84 \pm 5.172\%$ after 8 weeks' post-treatment with $P < 0.05$ as shown in (table 2).

The mean value of waist circumference was decreased significantly from 111.7 ± 14.06 cm at baseline to 90.60 ± 13.07 cm after 8 weeks' post-treatment with $P < 0.05$ as shown in (table 2).

The mean value of pain score percentage was decreased significantly from 94.00%. At baseline to 20.50% after 8 weeks' post-treatment, as $P < 0.05$.

In the control Group (GB), It was found that the mean value of weight was decreased significantly from 111.6 ± 24.21 kg to 104.8 ± 23.36 kg after 8 weeks' post-treatment, as $P < 0.05$.

The mean value of BMI was decreased significantly from 43.33 ± 6.378 kg/m² at baseline to 40.65 ± 6.155 kg/m² after 8 weeks' post-treatment, as $P < 0.05$.

Results showed a significant reduction in the mean value of abdominal obesity from 49.38 ± 6.274 % to 45.00 ± 6.124 % after 8 weeks' post-treatment with $P < 0.05$ as shown in (table 3).

The mean value of waist circumference was decreased significantly from 107.0 ± 14.41 cm at baseline to 101.3 ± 14.03 cm after 8 weeks post treatment with $P < 0.05$ as shown in (table 3).

Results showed a significant reduction in the mean value of pain score percentage from 94.50% At baseline to 42.00% after 8 weeks post treatment, as $P < 0.05$.

Between Groups:

The intergroups comparison of the weight and BMI results showed no statically significant differences at baseline and after 8 weeks post treatment with $P > 0.05$ as shown in (figure 1).

The intergroups comparison of the Abdominal obesity and waist circumference results showed no statistically significant differences at baseline with $P > 0.05$. However, after 8 weeks of treatment there was statistically significant difference in favor of group A when compared with group B with $P < 0.05$ as shown in (figure 2).

Finally, the intergroups comparison of the pain score percentage results showed no statistically significant differences at baseline and with $P > 0.05$. However, after 8 weeks of treatment there was statistically significant difference in favor of group A when compared with group B with $P < 0.05$ as shown in (figure 3).

DISCUSSION:

Low-level laser therapy (LLLT) is commonly used in medical applications, but scientific studies of its effect on losing body fat contouring are lacking⁽¹⁶⁾. The present study was designed to determine the effect of LLLT on reducing the abdominal obesity in women with lumbar disc prolapse.

All subjects were recorded medically free except for the lumbar disc prolapse L4, L5 to avoid any other impacts of systemic disorders on the subjects and their possible effect on the tested clinical parameters. Baseline, statistical analysis of data revealed no significant differences between both groups in terms of age, height, weight, BMI, abdominal obesity, waist circumference and pain measurements. Results after application of LLLT showed significant difference.

No side effects were reported related to LLLT that was used twice weekly at any time through the 8 weeks' study period. This was consistent with *croghan et al., 2020*⁽²⁰⁾ who reported no side effects with LLLT in all three treatment conditions namely, once, twice or three times weekly.

Overall satisfaction was higher among participants assigned to twice-weekly treatments than the other groups. On other hand this was inconsistency with *Jankowski et al., 2017*⁽²¹⁾ who used LLLT of 650 nm and 100 mw three days per week for two weeks and reported some side effects such as erythema lasting more than 24 hours, which may be due to the higher power output and in three times per week.

The results of the current study were in agreement with *Kennedy et al., 2015*⁽²²⁾ who compared the application of LLLT on subcutaneous fat reduction and body contouring with cryolipolysis, ultrasound and radio frequency and stated that these multiple non-invasive devices have consistently proven to be effective for circumferential reduction of local fat tissue by 2 cm or more, without any serious or permanent adverse effects. Also the results of the current study are consistent with *Mcrae and Boris, 2013*⁽²³⁾ as they reported a significant reduction in the circumferential measurements across waist by diode laser with wavelength 635nm, three times a week for two weeks.

Based on *Roche et al., 2017*⁽²⁴⁾ results, LLLT is considered by the united states of America Food and Drug Administration as a noninvasive esthetic treatment for reduction of circumference of hips, waist, and upper abdomen when applied to individuals with a BMI between 30 and 40 kg/m². This was in agreement with the results of the present study as they conducted a randomized, double-blind sham-controlled study on obese, but otherwise healthy, individuals who were randomized to undergo 30-min LLLT ($n = 28$) or sham treatments ($n = 25$) three times weekly for 4 weeks. Body measurements were obtained after 2 and 4 weeks of treatment and 2 weeks' post-treatment.

Said and Elnhas, 2016⁽²⁵⁾ supported the results of this study as they conducted a study on forty women with abdominal obesity, with application of 650 nm red laser light, output power 1.4-won abdomen for 30 minutes, two sessions per week for 6 weeks and concluded that LLLT can improve blood lipid profile as well as decrease of the waist circumference in women with abdominal obesity which may decrease risk of cardiovascular disease.

Recently *Croghan et al., 2020*⁽²⁰⁾ performed a pilot study on sixty overweight (BMI) 25-29.9kg/m² participants who were randomized to (group A) three times weekly for 4 weeks, (group B) twice weekly for 6 weeks, or (group C) once weekly for 12 weeks. They found that, participants receiving two LLLT sessions per week for 6weeks (group B) experienced greater reduction in weight and body fat mass at 6 weeks compared to those receiving three LLLT sessions per week for 4 weeks (group A). Their results showed that, LLLT was associated with reduction in weight, BMI, waist circumference and body fat mass. Participants in this pilot project demonstrated that these effects may be ideally achieved when they are delivered twice weekly. These findings are consistent with the results of the present study.

On the other hand, the present study results were inconsistent with *Elm et al., 2011*⁽²⁶⁾, as they evaluated the efficacy of low level laser for body contouring and circumference measurements on only seven subjects and revealed no statistically significant reduction at either 7days or 1-month post treatment. The difference may be attributed to the small sample size.

Also *Zhang et al., 2008*⁽²⁷⁾ results were inconsistent with the results of the present study as they concluded that, LLLT with 685 nm wavelength and 30mw show no significant effect on reducing body weight but it may be due to using of acupuncture application of laser on certain acupuncture points, but recently *Sebayang et al., 2020*⁽²⁸⁾ proved that Laser acupuncture significantly lower body mass index (BMI) by reducing abdominal and visceral adipose tissue content.

Arzpeyma et al., 2016⁽²⁹⁾ and *Sheng et al., 2017*⁽¹⁵⁾ noted the positive and significant association between obesity and disc degenerative changes in lumbar spine. Since there is abundant evidence in the literature demonstrating the strong association of disc degeneration on MRI with low back pain, prevention and treatment of being overweight or obese must be a public health priority which is done in our study by using LLLT in reduction of abdominal obesity which considered one of the biggest factors leading to lumbar disc prolapse.

In this study the non-significant difference between groups in all parameters in our study may be due to the small sample size or the low caloric diet used.

The current US guidelines for clinical weight management recommend a six-month weight loss goal of 3–5% from baseline weight⁽³⁰⁾, this modest weight loss can produce health benefits, with larger weight loss producing greater benefits. In the current study, both groups were able to achieve this, but group A who received LLLT and energy restricted diet showed a higher significant reduction of abdominal obesity and waist circumference which lead to significant reduction in pain with patients suffering from lumbar disc prolapse in compare to group B who received only diet regime.

Conclusion:

A combined treatment of LLLT for 20 minutes/ session, two sessions per week for 8 weeks” and diet regime restricted to 1200KCAL per day decreased significantly weight, waist circumference, abdominal obesity and pain for obese patient with lumbar disc prolapsed and considered a safe and effective treatment modality.

Source of funding

This study received no financial support.

Conflict of interest

The authors have no conflict of interest to declare.

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Figure (1) Inter-group comparison of mean values of weight and body mass index

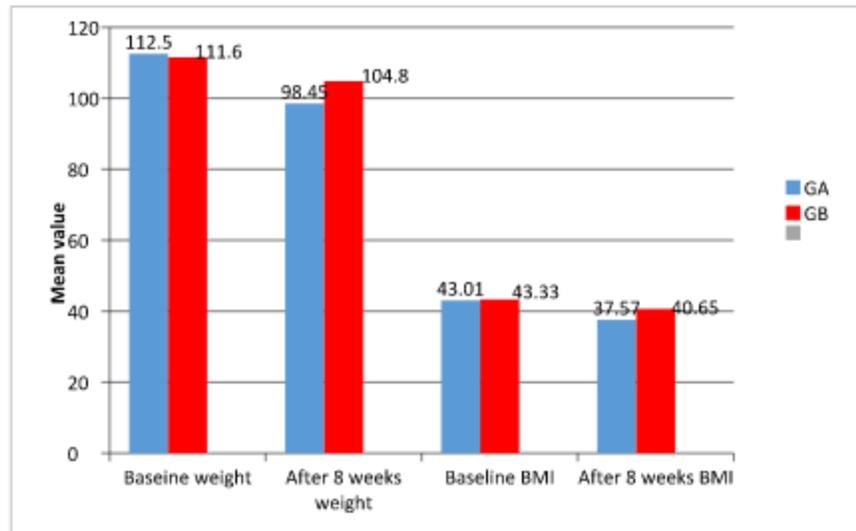


Figure (2): Inter-group comparison of mean values of abdominal obesity and waist circumference (WC).

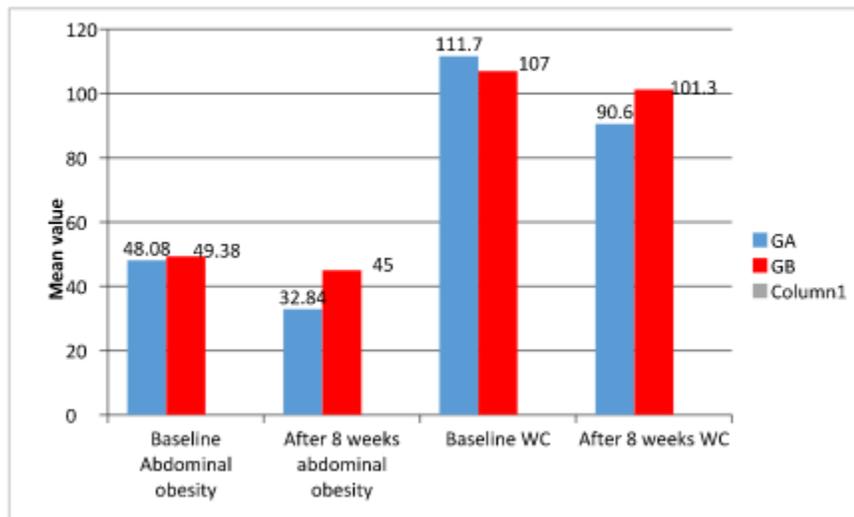


Figure (3): Intra-groups and inter-groups comparisons of pain score percentage

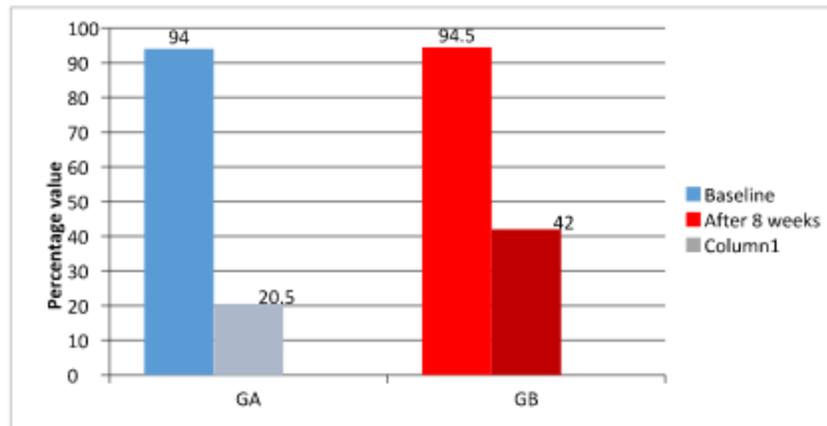


Table (1): Comparison of mean values of baseline data between groups A & B:

Group	Age		Height		Weight		BMI		AO		WC		Pain score %	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
M+SD	34.05 ± 2.41	34.15 ± 2.54	161.4 ± 7.51	160.0 ± 7.43	112.5 ± 23.25	111.6 ± 24.2	43.01 ± 6.438	43.33 ± 6.378	48.08 ± 6.107	49.38 ± 6.274	111.7 ± 14.06	107.0 ± 14.41	M	
t-test	0.1276		0.5712		0.1133		0.8744		0.6665		1.044		X ²	
p-value	0.8992ns		0.4080ns		0.9104ns		0.1591ns		0.5091ns		0.3031ns		0.9984ns	

Significance: p* < 0.05, p** < 0.01, p*** < 0.001 ns = not significance AO = abdominal obesity
 WC = waist circumference BMI = body mass index && = chi-square test

Table (2): Comparison of mean values of abdominal obesity and waist circumference in study group (GA):

	Abdominal obesity		Waist circumference	
	Baseline	After 8 weeks	Baseline	After 8 weeks
M+SD	48.08 ± 6.107	32.84 ± 5.172	111.7 ± 14.06	90.60 ± 13.07
paired t	10.76		21.08	
P	0.0001***		0.0001***	

ns = not significant Significance: p* < 0.05, p** < 0.01, p*** < 0.001

Table (3): Comparison of mean values of abdominal obesity and waist circumference in control group (GB):

	Abdominal obesity		Waist circumference	
	Baseline	After 8 weeks	Baseline	After 8 weeks
M+SD	49.38±6.274	45.00±6.124	107.0±14.41	101.3±14.03
paired t	5.385		13.66	
P	0.0001***		0.0001***	

ns=not significance Significance: p* $<$ 0.05, p** $<$ 0.01, p*** $<$ 0.001