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Post-Mastectomy Shoulder Pain and Lymphedema Responses to Ga-As Laser Versus Microcurrent Electrical Stimulation

Catherine Moanis Labib[1*], Prof Dr. Zakaria Mowafy Emam Mowafy[2], Prof. Dr. Ayman Abdel Samea Gaber[3], Assist Prof. Dr. Khadra Mohamed Ali[4]

[1]M.Sc. Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Cairo, Egypt.
[2] Professor, Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Cairo, Egypt.
[3] Professor of Surgical Oncology, National Cancer Institute, Cairo University, Cairo, Egypt.
[4] Assistant Professor, Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Cairo, Egypt.

Corresponding Author: Catherine Moanis Labib

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Abstract

Objective: *to evaluate the efficacy of GA-AS laser against microcurrent electrical stimulation on postmastectomy shoulder pain as well as lymphedema .**Method:** a double blinded randomized controlled study. sixty breast cancer patients with lymph-edema stage I and II ,40-55 years old were assigned randomly into study -group A, n = 20 or study -group B, (n = 20) in addition to control group C, (n = 20). The study group was given 20 minutes GA-AS laser, 90 minutes complete decongestive therapy (CDT). study -group B received 20 minutes of microcurrent electrical stimulation (MENS) and 90minutes CDT, control group C was given 90 minutes CDT. All treatment interventions were applied at a frequency of three sessions per week for 12 weeks. Arm volume calculated by circumference measurement, Shoulder and Hand (DASH) questionnaire as well as pain intensity utilizing a visual analogue scale (VAS) were measured at before and following 12 weeks of treatment . **Results**: a statistically significant difference has been detected in limb volume, DASH questionnaire as well as VAS favoring the study group A ((p = 0.001).) and the study group B ((p = 0.001). following 12 weeks of intervention. The mean (SD) for limb-volume, DASH questionnaire as well as pain score were 1236.74 ± 43.34, 27.21 ± 7.16, and 3.20 ± 0.62in the study group A, and 1331.76 ± 46.92, 34.52 ± 4.38 and 3.90 ± 0.78in the study group B and 1390.18 ± 58.77 ml, 40.68 ± 6.93and 5.30 ± 0.86in the control group C respectively. **Conclusion:** adding GA-AS laser and microcurrent electrical stimulation to the conventional physical therapy program had a valuable effect than traditional physical therapy program alone in improving postmastectomy shoulder pain as well as lymphedema.*

Key words *(GA-AS Laser, Microcurrent electrical stimulation, Postmastectomy shoulder pain, Lymphedema, Visual analogue scale and Volumetric lymphedema measurement).*

1. Introduction

When lymphatic flow is blocked, protein-rich lymphatic fluid builds up in the soft tissues, causing an increase of 2 centimeters or more in the circumference of the involved limb [1]. This syndrome is identified as breast cancer-related lymphedema (BCRL). Axillary lymph node dissection, a high quantity of lymph nodes detached, and mastectomy all increase the risk of BCRL developing 2-10 years later [2,3]. Swelling, pain, discomfort, heavy, tight, shoulder stiffness, hypersensitivity, absence of sensation in affected limb, and deterioration in general daily functioning are all common signs of lymphedema [4]. Lymphedema can be managed with a combination of physical therapy and other procedures such surgery, oral medicines, low-level laser (LLL) therapy, weight loss, mesenchymal stem cell therapy, Kinesio taping, as well as acupuncture. [5]. Traditional management of lymphedema has consisted of complete decongestive therapy (CDT) [6]. Self-management of lymphedema is essential for preventing the condition from worsening, avoiding recurrent infections, and preserving quality of life [7]. Components of CDT have been demonstrated to be beneficial in reducing swelling at first [8, 9], reducing symptoms, and increasing quality of life [10].

LLLT (BPM) is a non-invasive phototherapy modality that employs light with wavelengths within 650 and 1000 nm to provide low irradiance and dosages to the affected tissue [11]. Recent research has shown that LLLT may be an effective method of treating lymphedema. It has been shown to reduce volume by methods such as stimulating lymphatic motility and promoting lymph angiogenesis, without significantly altering tissue architecture. Additionally, LLLT would decrease the interstitial fibrosis that is associated with lymph stasis, which would increase lymphatic flow [13]. This method has been confirmed as being safe technique [12].

Musculoskeletal pain can be reduced by microcurrent therapy (MT), an electrotherapeutic method. It sends a subsensory electrical current (1 mA) through the skin, which does not cause muscle contraction. There is evidence that very low electric currents can increase the production of proteins, amino acid transport, as well as adenosine triphosphate (ATP) formation in tissues. Microcurrent electrical stimulation, as described by Sebastian et al. (23), has been shown to accelerate up cutaneous wound healing by decreasing inflammation and increasing angiogenesis (14).

In spite of the growing popularity of GA-AS laser and MT in the treatment of lymphedema and pain, there is no strong evidence recommending the utilization of microcurrent electrical stimulation and studies comparing the effectiveness of these treatment tools are inadequate. So, the purpose of our study was to determine and compare the clinical effects and efficacy of GA-AS laser and MT for patients with shoulder pain post mastectomy lymphedema.

Material and Methods:

Study design

It was a prospective, single-blinded, parallel-group randomized controlled trial carried-out among 2021 and 2023.

Participants

Sixty women were chosen from the National Cancer Institute in Cairo and treated at Eden Health Care, Cairo, for a year. the Study [012/003506] received approval from the Physical Therapy Department's Ethical Review Board and the trial was registered in clinical trial registry ID :[NCT05870241]. Before participating in the study, participants were screened to ensure they met the criteria and completed a written consent form. Stage I-II lymphedema (defined as a difference in circumference of up to 2 centimeters between the affected arm and the unaffected arm) was required for inclusion, as was a history of breast cancer that necessitated unilateral removal of the axillary lymph nodes. [15]. Stage I lymphedema, as described by the International Society of Lymphology, is characterized by the first manifestation of the swelling, which is apparent but disappears away when the affected arm is elevated. It's possible that there's pitting. Stage II lymphedema is identified by a consistent reduction in arm volume and the development of pitting. Tissue fibrosis develops with time [16], and elevation does little to alleviate the swelling**.**

Patients' medical histories were taken in great detail, including the side of the body affected, the type of surgery performed, the number of lymph nodes removed, the radiotherapy technique utilized, the systemic adjuvant treatment, the length of time of lymphedema, any prior episodes of infection, and whether or not all adjuvant treatment had been completed excluding hormone therapy. Cancer recurrence, current oncological treatment, functional impairments preventing participation in the exercise programs, as well as open wounds of any type were all reasons to rule out a patient from participation**.**

Randomization

The patients were informed of the study's goals, its potential benefits, their ability to opt out at any time, and the confidentiality of their personal information. All data anonymity is preserved through encoding. Utilizing computer-generated randomization blocks, individuals who had mild to moderate lymphedema were randomized into three groups (A, B, and C). The 1st author, who did not participate in data collection, developed the randomization. No patients left the study after being assigned.

Sample size calculation

Before enrolling participants, we used G*POWER statistical software (F tests, multivariate analysis of variance [MANOVA]: repeated measures within as well as among interaction measurements) to set the needed number of patients to detect an impact at the 0.05 level of significance (limb volume measurement), assuming an effect size of 0.27 and power of 0.8. A sample size of 60 was determined to be adequate for this study.

Intervention

Patients were randomized into one of three groups: a, b, or c. There were 20 female BCRL patients, aged 40 to 55, in each group. The patients in the Study group (A) twenty patients underwent complete decongestive therapy program plus GA-AS laser therapy. Treatment with lasers focused on three spots in the antecubital fosa and seven locations in the axilla, in which the lymph nodes had concentrated. Average power was 5mW, peak frequency was 2800Hz, pulse width was 50nm, average dose was 1.5 J/cm2, and exposure time for each location was 2 minutes [17] for a total of 20 minutes for 12 weeks, with 3 times per week.

The patients in the Study group (B) twenty patients underwent complete decongestive therapy program plus MENS. The treatment technique of MENS involves the application of eight sets of electrodes and a pair of manuals to the patient's skin at locations that match lymph nodal sites. Slow, circular strokes are used to apply pressure in a non-pressing manner along the body's lymphatic pathways. A patient may experience a tingling or warmth during treatment, but there will be no pain. Treatment for lymphedema of the upper extremities typically takes around 20 minutes to apply. The low offset voltage is constantly between +12 and 12 V (29), and the treatment is affected by a wave with a carrier frequency of 0.31 to 6.16 Hz and a modulation of 400 to 2120 Hz. Each participant in this study attended a total of thirty-six sessions over the course of three months, with sessions occurring every other day throughout the week.

The patients in the control group (group c) were given complete decongestive therapy that involved manual lymphatic drainage, compression bandaging, exercise to improve lymphatic drainage as well as Skin Care.

Manual lymphatic drainage was reported to be efficient in decreasing edema and edema-related symptoms (18,19). involves the therapist making motions with their hands on the patient's skin as well as subcutaneous tissue. We are using extremely light pressure. Applied motions are slow to accommodate the lymphatic pulse beat. The order of application of all techniques is distal-to-proximal (18). It takes 45 minutes for each limb. Finger and hand pressures of 30-45 mm Hg are recommended for optimal results during manual lymphatic drainage. (19).

Bandaging techniques using compression short stretch bandages are used to apply compression. High working pressure and primary reliance on runner strength for muscular system (19) characterize short-stretch, inelastic bandages. After massage, a compression bandage is applied from the extremity closer to the heart to force fluid to move in a different direction and away from the edematous area (20). Compression bandages are effective in reducing swelling and associated pain when used as directed. Bandages come in a variety of sizes, with the largest providing pressure of between 20 and 30 mmHg. (21).

Exercise is sometimes used therapeutically to reduce lymphedema volume and influence lymphatic function. There are four primary types of therapeutic exercise. Regarding lymphedema therapy, these healing exercises involve a sequence of extremely specialized physical activities designed to improve the rhythmic as well as sequential muscle contractions in the affected area. put on the arm by means of external compressions (which is frequently armbands and bandages). (19). Aerobic exercise improves lymphatic drainage by vigorously pumping the proximal vessels, resulting in a higher negative pressure. The effects of aerobic exercise can be increased by applying external compression at the same time (22, 23,19)., soft resistance Muscles' inherent ability to perform daily tasks may benefit from strength training. It aids in the gradual improvement of muscular strength and toning. The range of motion of the muscles should be gradually increased during resistance training (23)., and Lymphedema and proximal limb swelling can be managed by performing range of motion exercises on all affected joints. Regular stretching and other flexibility exercises can improve biomechanics, aid in the development of good posture, lessen fibrosis, and stimulate lymph movement. Exercises that increase range of motion can reduce the formation of scar tissue, which can impede lymph flow (22, 23, 19). To achieve the most possible benefit, each of these methods should be skillfully involved in a comprehensive plan. (24,24).

Skin Care: main aims of skin care are reducing microbial colonization of the dermis, eliminate bacterial and fungal spread of chaps, curb dryness by increased fluid intake, and eliminate chaps. Moisturize your skin and keep it from breaking out with daily washings with oil-based mineral soaps (19, 26). the frequency of this treatment protocol for each patient of this group was three times a week, every other day, over a course of three months.

Outcome measures

The outcome measurements included the VAS for pain evaluation, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, as well as the circumference-based limb volume calculation. A physiotherapist did an evaluation before and after the procedure.

Limb volume measurement

The volume of the limbs was used as the primary outcome to assess the effectiveness of the treatment. This was done by calculating the average circumference of the shortened region of the limb across two successive circumferences. The segment's volume was determined using the formula V=h (C12 +C1C2+C22)/12 [27], in which V is the volume while C1 and C2 are the beginning and ending circumferences of the section, while h is the distance that exists among them. The patient was seated comfortably, and the circumference was taken with a regular 1-cm retractable fiberglass tape. The limb was positioned on a bedside table, as well as an adhesive measurement strip was used to secure it at regular 10-centimeter intervals throughout its length, from the axilla to the wrist. Starting at the ulnar styloid process, 10, 20, 30, and 40 cm of proximal distance were measured [28].

VAS for pain assessment

Intensity of pain was also measured as a secondary outcome of treatment. Adults, particularly those with chronic pain, frequently use the one-dimensional VAS. The VAS consists of a vertical (VVAS) or horizontal (HVAS) line, usually 10 cm long, with two verbal descriptions at either end, one for each intensity of the symptom. Patients were given clear instructions, given a timeline for reporting, and given verbal description anchors to use during the measuring process. [29].

The Disability of Arm, Shoulder and Hand Questionnaire (DASH)

it is a standardized tool for assessing the impact of arm, shoulder, as well as hand impairments on daily life, including limitations on work as well as leisure activities. (The possible answers range from 1 to 5: 1 = no difficulty, 2 = mild difficulty, 3 = moderate difficulty, 4 = severe difficulty, and 5 = are unable to do. A high DASH score means significant disability, with scores ranging from 0 to 100 for each module. The DASH has been proven to have strong construct validity, test-retest reliability, as well as responsiveness to change in studies including proximal and distal arm problems, as well as a variety of upper-limb problems, when administered in either the original English or its Swedish, Spanish, or French versions. Therefore, it is an effective, practical, as well as valid method of assessing the upper limb disability (30,31,32).

Data analysis

The subjects' characteristics were compared across groups utilizing an ANOVA test. The lymphedema stages and surgical procedures were compared between the groups using the chi-squared test. The data were checked for normality with the Shapiro-Wilk test. Levene's test for homogeneity of variances was used to check for group homogeneity. One-way analysis of variance (ANOVA) was used to compare the groups' VAS, DASH, as well as LVM scores. Following that, post-hoc testing employing the Tukey test were used to conduct multiple comparisons. A paired t test was used to compare the conditions of each group before and after treatment. The level of statistical significance used in all analyses was p <0.05. The study was conducted using IBM SPSS Statistics Version 25 for Windows (Chicago, Illinois, USA).

Results and Discussion

- Subject characteristics:

Sixty individuals with post-mastectomy shoulder pain as well as lymphedema were included in this study were ranged from 40 to 55 years. The ages of the three groups are listed in Table 1. Subject characteristics did not differ significantly ($p > 0.05$) among groups.

Table 1. Basic characteristics of participants.

	Group A	Group B	Group C	p-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age (years)	49.20 ± 4.16	49.25 ± 4.13	49.30 ± 4.66	0.99
Weight (kg)	77.30 ± 12.90	77.20 ± 10.59	75.65 ± 12.23	0.**88**
Height (cm)	159.85 ± 6.03	161.60 ± 4.68	161.30 ± 4.93	0.**53**
BMI (kg/m²)	30.17 ± 4.07	29.52 ± 3.49	28.97 ± 3.64	0.**59**

Time since surgery (months)	23.50 ± 11.14	26.70 ± 8.62	24 ± 12.62	0.61
Number of lymph node resection	13.80 ± 3.39	15.60 ± 4.56	13.05 ± 3.89	0.12
Number of radiation therapy	19 ± 4.88	16.45 ± 6.15	18.80 ± 4.71	0.24
Number of chemotherapies	6.65 ± 2.58	6.85 ± 2.25	6.35 ± 2.43	0.81
Lymphedema stage, n (%)				
Stage I	11 (55%)	**9** (**45**%)	10 (50%)	0.82
Stage II	9 (45%)	**11 55**%)	10 (50%)	
Type of surgery, n (%)				
Modified radical mastectomy	10 (50%)	11 (55%)	13 (65%)	0.62
Partial mastectomy and lymph nodes resection	10 (50%)	9 (45%)	7 (35%)	

SD, standard deviation; p-value, level of significance

Effect of treatment on VAS, DASH and LVM:

Within group comparison

After treatment, all three groups revealed statistically significant reductions in VAS, DASH, in addition to LVM in comparison with their baseline values ($p < 0.001$). In groups A and C, the VAS decreased by 63.64 percent, while group B saw a 55.43 percent reduction and group C experienced a 38.01% reduction. Reductions in DASH were highest (60.44%) in Group A, followed by Group B (52.41%), and Group C (43.37%). Reductions in LVM of 36.06, 32.04, and 28.37% were observed in Groups A, B, and C, respectively. (Table 2).

Between group comparison

Before treatment, there was no statistically significant difference among the groups. Post-treatment comparisons between groups showed that VAS, DASH, in addition to LVM were significantly reduced in Group A in comparison with Group B ($p < 0.01$) as well as Group C ($p < 0.001$), and that VAS, DASH, in addition to LVM were significantly reduced in Group B in comparison with Group C ($p < 0.01$). (Table 2).

Table 2. Mean VAS, DASH and LVM before and after treatment of group A, B and C:

	Group A	Group B	Group C	p-value		
	mean ± SD	mean ± SD	mean ± SD	A vs B	A vs C	B vs C
VAS						
Pre treatment	8.80 ± 0.69	8.75 ± 0.96	8.55 ± 0.68	**0.97**	**0.71**	**0.58**
Post treatment	3.20 ± 0.62	3.90 ± 0.78	5.30 ± 0.86	0.01	0.001	0.001
MD	5.6	4.85	3.25			
% of change	63.64	55.43	38.01			
t- value	36.78	29.11	11.61			
	p = 0.001	p = 0.001	p = 0.001			
DASH						
Pre treatment	68.78 ± 8.79	72.53 ± 8.96	71.83 ± 5.64	0.30	0.45	0.95
Post treatment	27.21 ± 7.16	34.52 ± 4.38	40.68 ± 6.92	0.002	0.001	0.008
MD	41.57	38.01	31.15			
% of change	60.44	52.41	43.37			
t- value	25.48	16.17	22.52			
	p = 0.001	p = 0.001	p = 0.001			
LVM (ml)						
Pre treatment	1934.35 ± 176.39	1959.60 ± 145.44	1940.73 ± 166.93	0.**87**	0.9**9**	0.9**2**

Post treatment	1236.74 ± 43.34	1331.76 ± 46.92	1390.18 ± 58.77	0.001	0.001	0.001
MD	697.61	627.84	550.55			
% of change	36.06	32.04	28.37			
t- value	17.75	18.79	18.51			
	p = 0.001	p = 0.001	p = 0.001			

SD, Standard deviation; MD, Mean difference; p-value, Level of significance

Discussion

The finding of this study revealed that there was a statistically significant revealed a decline in VAS, DASH and LVM of group A in comparison with that of group B ($p < 0.01$) and group C ($p < 0.001$) and a significant decline in VAS, DASH as well as LVM of group B compared with that of group C ($p < 0.01$).The findings of the present study might prove that LLLT therapy have greater effective strategies on decrease (pain, DASH scale and lymphedema) than MENS as well as conventional physiotherapy program.

In 1995, Piller and Thelander [33] suggested LLLT as a possible treatment for lymphoedema. Multiple published clinical investigations, cell and tissue research, and animal studies have since shown promise for LLLT as a treatment for lymphatic diseases. The effects of LLLT on fibroblasts [35] have led to its use in the management of fibrous scar tissue [34]. These outcomes matter for the treatment of both the brawny edema that frequently occurs in lymphedematous limbs in addition to the surgical scars caused by PML [37]. LLLT has been suggested to promote lymphogenesis and increase lymphatic motoricity [36]. Macrophage cells may be affected by LLLT, and the treatment appears to activate the immune system. [38].

This study was carried-out to evaluate the effectiveness of GA-AS laser versus microcurrent electrical stimulation on postmastectomy shoulder pain and lymphedema. Most of previous studies focused on the efficiency of low-level laser therapy with other modalities but no study focused on comparison effect between them. The findings of this study came in agreement with other studies that found LLLT superior to CDT for the decline (pain, DASH scale as well as lymphedema).

In a 2009 single-blind study using scanning LLLT, Rufina W.L. Lau et al. [39] recruited 21 patients. Patients were given 2 jcm2 of scanning laser energy applied to the area around their axillas for 20 minutes. The treatment program involved three sessions a week for four weeks, with a four-week follow up post treatment. After 4 weeks of LLLT, patients experienced a 16% decline in volume, and this increased to 28% in the follow-up period. At the subsequent evaluation, the placebo group's limb volume had increased by 6%.

A case series involving 12 patients was published in 2009 by Wigg [40]. Patients with thickening that did not respond to standard treatment were enrolled for the trial. For 7-25 minutes, patients were exposed to a pulsed 904nm laser at 1 or 1.5 jcm2. Three times weekly for two weeks, once weekly for 4 weeks, twice monthly, and once every two months, respectively, were the treatment intervals followed. The results were positive, with 100% of patients reporting significant enhancement.

The use of a multifrequency scanning laser to treat the PML arm as well as the anterior chest has shown promising first results [41]. We aimed to determine if applying a laser of a single wavelength directly to the axilla would be effective. The axillary region, which contains many lymph nodes from which lymph drains mostly from the upper limb in PML patients, is thought to be the site of lymphatic drainage obstruction. We hypothesized that the laser could help resolve the lymphedema by decreasing fibrosis and activating preexisting lymphatic drainage channels, stimulating the development of new pathways, and/or stimulating a localized lymphocyte reaction.

Nonetheless, when compared with laser therapy, manual lymphatic drainage (MLD) [42] has found to be an efficient therapeutic and rehabilitative approach. Arm volume can also be decreased by participating in rehabilitative activity, performing complex decongestive treatment (CDT), and wearing multi-layer bandaging for compression [43]. However, a significant change in arm volume is produced when these therapies are combined with LLLT.

Although the WALT [44] text makes it clear that wavelength, proper dose, as well as duration of laser therapy should all be regulated variables, the authors were unable to provide a full description of these factors in RCTs. Other reviewers have also noticed these problems [45], therefore this is not unusual. In addition, it is challenging to aggregate data on LLLT (PBM) use due to differences in treatment techniques, methodologies, application locations, as well as changeability among the components. This will lead to inconsistent results unless a corresponding WALT recommendation is followed to the letter. In the studies that reported RCTs, researchers typically used light with a wavelength between 808 and 980 nanometers and an energy density of 1.5 to 4.89 joules per centimeter squared (J/cm2). Similarly, effective power concentrations for tendinopathy range from 1.8 to 19.2 J/cm2 based on the tendon location [46].

The findings of this study came in accordance with other studies that found MENS superior to CDT for the decrease (pain, DASH scale and lymphedema).

While the precise methods by which MT helps lymphedema patients remain unknown, it is thought that the increased ATP production that results from the microcurrent electrical stimulation accelerates up the body's natural process of healing damaged tissues. The mitochondrial electron transport chain has been hypothesized to be stimulated by MT, leading to increased ATP production [47]. The transfer of extracellular calcium ions across the cell membrane affected with the microcurrent, which in turn increases intracellular calcium levels and increases ATP production. Protein synthesis is ultimately stimulated by DNA-control systems, which leads to reduced inflammation and more cellular repair [48].

The intensity of MT is proportional to its therapeutic impact. The recovery of injured tendons and ligaments was found to be enhanced by low-intensity electrotherapy in a prior study [47]. Tendon healing in persistent cases of tennis elbow was found to benefit more from 50 A than from 500 A in a recent study**.[48]**

In a rabbit model of a rotator cuff full-thickness injury, Kwon and Moon discovered that 60 minutes per day of microcurrent (intensity 25 A, frequency 8 Hz) for 4 weeks accelerated the healing process **.**

[49].

Previous research has shown that low-amperage currents, such the 25 A microcurrent electrical stimulation we used for secondary lymphedema, can stimulate tissue regeneration. The microampere level of MT's operation, which is similar to the electrical intensity found in live tissues, likely explains why no negative side effects were recorded. In order to treat lymphoedema, Ricci [17] examined the effectiveness of a low-frequency, low-intensity electrotherapy (LFLIE) device which activates the lymph's biological structures using bioresonance. Fifty patients received this treatment, and its efficacy was confirmed using lymphoscintigraphy. The treatment increases lymph flow, stimulates apical limb lymph nodes, and decreases cutaneous back flow, according to the study's findings. According to their findings, the LFLIE device successfully reduced both volume and the 'feeling of gravity as well as hardening.

Patients suffering from lymphoedema related to breast cancer were studied by Roser [50]. et al, who compared low-frequency, low-intensity electrotherapy versus MLD for numerous important outcomes. Despite the fact that there were no significant differences between the treatments, the tendency toward improved health-related QOL after receiving LFLIE was apparent.

Our findings indicate that low level laser may be more effective method than MENS as treatment modality for secondary lymphedema.

Limitations of the study:

This study had some limitations: psychological and physical state of the patients during the treatment period; small sample size. other measurement tools might be necessary to achieve maximum reliability. It is also important to study the long-term outcomes to evaluate the impact of the treatment modalities.

Conclusion

This study's findings indicate that LLLT was efficient in individuals with BCRL reduce swelling in affected limbs, decrease the intensity of pain, and improve their scores on the DASH questionnaire.

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