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Original Article

Can Low Level LASER Therapy be used as a practical alternative to Combined Decongestive Therapy in young female patients with post-mastectomy Lymphedema?

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Keywords

Combined Decongestive therapy,
Low level LASER,
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ABSTRACT

Purpose: to compare the effect of LLLT versus CDT in terms of limb volume, quality of life & treatment time.
Patients & Method: 40 postmastectomy females with unilateral BCRL. They were randomly divided into 2 equal groups; group (A) received CDT. Group (B) received LLLT. Both groups were treated 5days/week for 4 weeks. Circumference tape measuring. Health Related Quality of life (HRQL) assessment by upper Limb lymphoedema-27 questionnaire. Pre & Post- treatment measures were compared. Stop watch used.
Results: The percentage reduction of affected limb volume was not significantly better in group A (16.158 % from2723.69 ± 324.91 cc to 2283.58 ± 311.63 cc) compared to 8.21 % (from 2807.98 ± 424.943 cc to 2577.478 ± 389.646 cc) in group B (p-value 0.16). The percentage improvement of HRQL physical score was 15.81% in group B which is border line significantly less than improvement in group A (38.42%), p-value = 0.05. The percentage improvement in HRQL psychological score was not significantly different between both groups (in group A = 12.3% compared to 14.28 % in group B, p-value = 0.92). The percent improvement of HRQL social score (21.08 % in group A) is border line significantly better than group B (12.6%), (p-value = 0.08). The time needed for CDT ranged from 65 to 80 minutes (mean = 72.95 +/- 4.93 min.), while LLLT application time was 20 - 23 min. (mean = 18.5 +/- 1.12) which is highly significantly shorter (p-value < 0.000**).
Conclusion: LLLT saves time. Recommended in high workload centers

INTRODUCTION

One of the most distressing complications of the long-term health problems facing breast cancer patients is breast cancer-related lymphedema (BCRL). It was found that mastectomy accompanied by axillary node dissection and radiotherapy impairs lymphatic drainage of the affected upper limb, and place patients at risk for secondary lymphedema, which has been reported at rates ranging from 10.0% to 49.0%. This disorder, which often appears after breast cancer treatment is gradual, chronic, progressive and also resistant to treatment (1)(2)

Lymphedema is swelling that occurs when protein-rich lymph fluid accumulates in the interstitial tissue caused by an abnormality of the lymphatic system. This lymph fluid may contain plasma proteins, extravascular blood cells, excess water, and parenchymal products. Lymphedema is one of the most poorly understood, relatively underesti-

mated, and least researched complications of cancer or its treatment (3)

Left untreated, lymphedema leads to chronic inflammation, infection and hardening of the skin that, in turn, results in further lymph vessel damage and distortion of the shape of affected body parts(4)(5)(6) .One complication of lymphedema is the development of fibrosis in which the skin and underlying tissues of lymphedematous regions become hardened(7)

It was reported that experts who treat lymphedema consider combined decongestive therapy (CDT) which is also called complex decongestive physiotherapy (CDP) the "gold standard" of treatment and consider it the main treatment for lymphedema(8) (9) (10)

CDT consists of four main components: skin care (moisturizing the skin; protection from infection and trauma), manual lymph drainage, compression (short stretch multi-layer bandage technique) and exercise are applied in an intensive treatment program until the difference in arm circumference is reduced in patients. It remains to be the cornerstone of therapy in all patients suffering from lymphedema(11)(12).

Low level laser therapy (LLLT) (wave lengths 650-1000 nm) is a U.S. Food and Drug Administration (FDA)-approved therapeutic intervention for treatment of arm lymphedema. LLLT is believed to stimulate lymphatic motility (movement), lymphangiogenesis, and macrophage activity, and soften fibrotic tissues, improving contractility in the tissues that assist with lymph transport through the lymphatic vessels(13).

AIM OF WORK

The aim of this study was to compare the effect of LLLT versus CDT in management of young women (< 40 years old) with post-mastectomy lymphedema

PATIENTS AND METHODS

This study was conducted at physiotherapy unit at Kasr Alainy Center of clinical Oncology and Nuclear Medicine, Faculty of Medicine, Cairo University during a period from May 2015 until January 2016 and included forty females having unilateral post mastectomy grade 2 or 3 lymphedema according to NCI-CTCAE Scale. Patients aged less 30-40 years old. They participated in the study after signing institutionally approved consent. Patients were excluded if they were non-cooperative, have severe co-morbid diseases or they have cellulitis, bone metastases or any orthopedic problem of the affected upper limb. All patients were evaluated using circumferential measurement and health related quality of life (HRQL) assessment. Volume measurement was determined through circumferential assessment using a tape measure at predetermined sites on the involved versus the uninvolved limb. The sites of measurement were determined and standardized to be reference points. Anatomic landmarks were used, and measurements were taken in intervals along both limbs as according to Mahoney et al (14). The tape was disinfected using boiling water and Dettol between each measurement. Data was collected in an evaluation before treatment and after treatment. Patients were in the sitting position with their arms extended. Patient's upper limbs were marked with permanent marker at the sites mentioned below.

The flexible tape measure was approximated in the coronal plane at each level on the upper limb and pulled with a force that is snug on the arm but don't cause the skin to deform as shown in figure (1)

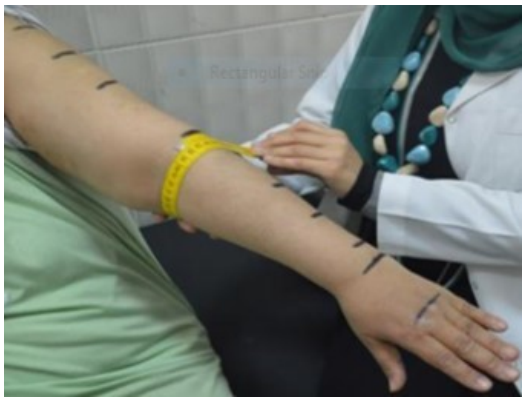

Fig. 1 Circumferential measurements of the arm

Circumferential measurements were entered into pre-programmed calculator to calculate limb volume and excess limb volume. according to Williams and Whitaker(15)

The ULL-27 is a self-report questionnaire encompassing 27 questions with answers given on a 5-point Linker scale, whereby 1 indicates 'no difficulty' and 5 indicates 'maximum difficulty' and was considered to measure the effects of lymphedema on HRQL. The questionnaire measured three domains: physical (15 items), psychological (7 items) and social (5 items) as shown in (figure 8) (16). Patients were divided randomly by using permuted block randomization method; into 2 equal groups as follow:

- Group A: Twenty patients with unilateral upper extremity lymphedema received CDT 5 days per week for 4 consecutive weeks.
- Group B: Twenty patients with unilateral upper extremity lymphedema received LLLT 5 days per week for 4 consecutive weeks.

CDT involved manual manipulation of the lymphatic ducts, short stretch compression bandaging, therapeutic exercise, and skin care. Manual manipulation of the lymphatic ducts consisted of gentle, rhythmic massaging of the skin which is intended by proponents to encourage the natural circulation of the lymph through the body and to stimulate the flow of lymph and its return to blood circulation with a pressure less than 9 ounces per square inch. Session involved drainage of the neck, trunk and involved extremity (in that order), lasting approximately 40 t0 60 minutes(17) .

The LLLT is Infrared (GA-AS) Laser Unit manufactured by Uniphy technology, Belgium. Laser Phyaction CL-904 as shown in figure (2a). The laser has a small hand held probe class 3B, laser product. It is a pulsed infrared Ga-As Laser device with pulse peak power of 13, 5 W, pulse frequency: 2-30,000 Hz, maximum average power of 70, 5

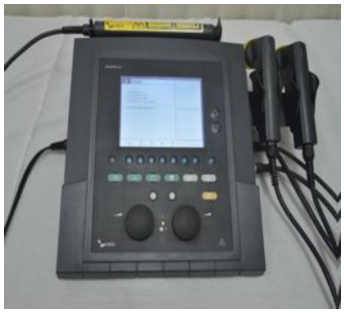

Fig. 2a Infrared (GA-AS) LASER Unit
Fig. 2b Protective eye glasses

Fig. 3. LASER application over the axillary area

mW and energy per pulse of 2, 35 mJ. Protective eye glasses (goggles) were worn during the application of laser to avoid permanent eye damage resulting from direct exposure to the laser beam as shown in figure (2b). Five points of the most tissue hardness were irradiated in the axillary region. The LASER treatment head was disinfected using Dettol before the starting and after the end of each session. The head was held in contact with, and at right angles to, the skin adjacent to each point (Figure 3). The device was switched on for 3:45 minutes per point, making the treatment time 17:25 minutes per session. The pulse frequency was 3000 Hz. The power output was 7mw. The total energy applied was 7.4 Joules, giving a dosage of 1.5 Joules/cm2 at each point. The treatment time was measured for each patient using stop watch & was documented

STATISTICAL ANALYSIS

Data were analyzed using SPSS program. Inferential statistics were used to analyze the data of the study and control groups. The collected data were statistically analyzed using descriptive statistics mean ± standard deviation (±SD). The level of significance < (0.05). P value less or equal to 0.05 was considered significant and less than 0.01 was considered highly significant

RESULTS

* Pre-treatment evaluation

There was no statistically significant difference between the two groups regarding age, weight, baseline limb sound, affected limb mean volume or HRQL scores as shown in table (1). The affected limb was 21.852 % larger than the sound limb in group A (p-value =0.000**) &

Table 1. Pre-treatment evaluation of both groups

	Group A	Group B	p-value
Age (years)	35.93±4.18	35.10±5.22	0.211
Weight (Kg)	76.4±9.37	73.4± 7.35	0.143
Axillary treatment:			
Surgery alone (no., %)	18, 90%	17, 85%	0.41
Surgery + axillary Radiotherapy (no., %)	2, 10%	3, 15%	0.76
No. of lymph nodes dissected (range, median, SD)	2-20, 10.5, 4.3	3-19, 9.5,4.6	
Sound limb volume (cm3)	2235.23 ± 269.96	2318.66 ± 263.08	0.606
Affected limb volume (cm3)	2723.69 ± 324.91	2807.98 ± 424.943	0.233
HRQL physical score	47.5 ± 16.122	44.9 ± 14.02	0.533
HRQL psychological score	19.5 ± 6.58	21.9 ± 6.6	0.314
HRQL social score	18.5 ± 3.19	17.45 ± 4.31	0.509

21.1 % larger than sound limb in group B (p-value = 0.000**).

*** After treatment**

1-Limb volume changes: In group (A), the mean value of total volume of the affected limb was significantly reduced from 2723.69 ± 324.91 cc to 2283.58 ± 311.63 cc with p-value = 0.000**. In group B, the mean value of total volume of the affected limb was also significantly reduced from 2807.98 ± 424.943 cc to 2577.478 ± 389.646 cc with p-value = 0. 000**. The percentage reduction was not significantly better in group A (16.158 %) compared to 8.21 % in group B (p-value 0.16) as shown in table (2)

Table 2. Mean values of swelling volume before starting and after the end of the study between groups (A&B).

	Group A	Group B
Pre treatment volume (cc)	2723.69 ± 324.91	2807.98 ± 424.943
Post treatment volume (cc)	2283.58 ± 311.63	2577.478 ± 389.646
Change (%)	16.158	8.21
p-value for change in the group	0.000**	0.000**
p-value for difference between both groups	0.16	

2- HRQL assessment

a- Physical score

as shown in table 3, In group (A), the mean value of physical score was significantly decreased after treatment (47.5 ± 16.122) when compared with its corresponding before treatment (29.25 ± 8.68), p- value = 0.001. The percent improvement was 38.42% in group A. In group (B), there was a statistical significant difference between the mean value of physical score measured before treatment (44.9 ± 14.02) and its corresponding after treatment (37.8 ± 13.66) p-value = 0.009. The percent improvement was 15.81% in group B which is border line significantly less than improvement in group B (38.42%), p-value = 0.05

Table 3. Mean values of HRQL- physical score before starting and after the end of the study between groups (A&B).

	Group A	Group B
Pre treatment volume (cc)	29.25 ± 8.68	37.8 ± 13.66
Post treatment volume (cc)	47.5 ± 16.122	44.9 ± 14.02
Change (%)	38.42	15.81
p-value for change in the group	0.001	0.009
p-value for difference between both groups	0.05	

b- Psychological score

In group (A), the mean value of psychological score was significantly improved after treatment (13.65 ± 6.26) when compared with its corresponding before treatment (19.5 ± 6.58), with p-value = 0.000. The percentage of improvement was 30% in group (A). In group (B) here was a statistical significant difference between the mean value of psychological score measured before treatment (21.9 ± 6.6) and its corresponding after treatment (15.6 ± 7.2) with p-value = 0.000. The percentage of improvement was 28.76% in group (B). The percentage reduction was not significantly different between both groups (in group A = 12.3% compared to 14.28 % in group B, p-value = 0.92) as shown in table (4)

Table 4. HRQL- psychological score for both groups (A&B) before starting and after the end of the study.

	Group A	Group B
Pre treatment score	19.5 ± 6.58	21.9 ± 6.6
Post treatment score	13.65 ± 6.26	15.6 ± 7.2
Change (%)	30	28.7
p-value for change in the group	0.000	0.000
p-value for difference between both groups	0.92	

c- Social score

Table 5 shows the following, In group (A), the mean value of social score was significantly decreased after treatment (14.6 ± 4.13) when compared with its corresponding before treatment (18.5 ± 3.19) with p-value = 0.000. The percent improvement was 21.08 % in group (A). In group (B), there was a statistical significant difference between the mean value of social score measured before treatment (17.45 ± 4.31) and its corresponding after treatment (15.25 ± 4.86), with p-value = 0.000. The percent improvement (21.08 % in group A) is border line significantly better than group B (12.6%), p-value = 0.08).

Table 5. HRQL- social score for both groups (A&B) before starting and after the end of the study

	Group A	Group B
Pre treatment score	18.5 ± 3.19	17.45 ± 4.31
Post treatment score	14.6 ± 4.13	15.25 ± 4.86
Change (%)	+12.6	+ 21.08
p-value for change in the group	0.000	0.000
p-value for difference between both groups	0.08	

3. Treatment time:
The time needed for CDT ranged from 65 to 80 minutes (mean = 72.95 +/- 4.93 min.), while LLLT application time was restricted to 17.75 min. resulted in a total session time from 20 to 23 min. (mean = 18.5 +/- 1.12) which is highly significantly shorter (p-value < 0.000**). In addition, LLLT requires less training to physical therapist.

DISCUSSION:

Lymphedema can be a serious and disabling complication and can cause significant psychologic distress(18). The aim of the present study was to objectively compare between the effect of LLLT versus CDT in young patients with post mastectomy unilateral upper extremity lymphedema, using the circumferential measurement as an objective tool to assess the upper extremity volume and the ULL-27 to assess HRQL. The results of this study revealed that both groups (A) and (B) showed a statistical significant improvement in circumferential measurements and HRQL post treatment, in comparison between both groups; the findings of this study demonstrated that the CDT group did not show a statistically significant greater improvement (p= 0.16), nor better improvement of the HRQL psychological score (p= 0.92). The superiority of CDT over LLLT is proven only in HRQL physical & social with border line statistical significance (p = 0.05 & 0.08 respectively). Treatment time was highly significantly shorter (p-value < 0.000**) in LLLT compared to CDT with the advantage of less training needed by physical therapist to handle the technique. Within the limitation of this study, there were a few studies concerning the scope of the comparison between LLLT and CDT to compare the present results within it. Another limitation of the study, the ULL-27 questionnaire has only been validated in French and Dutch (16).Many studies, Ridner et al., Kozanoglu E et al., Mazzotti E et al., (13)(19)(20) provided contradictory results regarding differences between LLLT and CDT for reducing limb circumference in BCRL. The studies by Kozanoglu E et al., Mazzotti E et al., (19)(20) showed significant superior effects of LLLT over compression bandage & pneumatic compression. A third study by Ridner et al., (13) did not show the superiority of LLLT over manual lymphatic drainage

The result of current study comes in support with the result stated by Gurdal SO et al., (21). The objective of this prospective controlled study was to assess the efficacy of two different combination treatment modalities of lymphedema. Manual Lymphatic Drainage (MLD) and compression bandage combination have been compared with Intermittent Pneumatic Compression (IPC) plus self -lymphatic drainage (SLD) in terms of arm circumferences measurements and HRQL assessment using the European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC-QLQ) and American shoulder and elbow surgeons (ASES) test. And the results were that both different treatment modalities appear to be effective in the treatment of lymphedema with similar therapeutic efficacy in patients with breast cancer.

The present study agreed with the finding of a previous study of Mazzotti E et al., (22) who demonstrated that after four weeks of CDT on post-breast cancer surgery lymphedema patients there was a clinical significant decrement in circumference at short and long-term effects, it also reported that the patients who have had an extra reduction showed a better HRQL which was rated using the Functional Assessment of Cancer Treatment-General scale (FACT-G) and the FACT-Breast cancer subscale (FACT-B+4).

The current study is consistent with the work of Ezzo J (23) who concluded that the application of MLD in addition to compression bandaging is safe and offers significant benefit for swelling reduction in BCRL patients. It also reported that compared to patients with moderate to severe BCRL, those with mild-to-moderate BCRL are the ones who benefit from adding MLD to an intensive course of treatment with compression bandaging. The current study is greatly consistent with Omar et al., (24) work who demonstrated that the use of Ga-As laser device that had wavelength of 904 nm, power of 5 mW and spot size 0.2 cm over the axillary and arm areas, three times a week for 12 weeks on fifty women with BCRL showed a significant improvement in reducing the limb volume, increase shoulder mobility, and hand grip strength. The result of the current study is to some extent in line with the systematic review done by Monterio et al., (25) who counted with a total of five studies to analyze the effects of LLLT on BCRL women. The systematic review concluded that the use of LLLT in women with BCRL displayed positive results, such as reduction in circumference of volume of the affected limb. Thus, it can be considered one more therapeutic option for managing this condition.

The current study agrees with the findings of a systematic review done by Lima et al., (26) who considered four studies on the use of LLLT in the treatment of lymphedema after breast cancer treatment. The result of this systematic review demonstrated that the LLLT showed favorable results in limb volume reduction, measured by perometry, bioimpedance, circumference of the upper limbs and water displacement, as compared with the control group. Also significant decrease in tissue hardness was observed.

Other studies showed superiority of LLLT like the study by White et al., (27)who conducted a study to compare the effect of LLLT with CDT for the initial treatment of BCRL. The patients received either two weeks of LLLT or CDT. A statistically significant reduction in arm circumference relative to the control group was noted after LLLT in participants with mild but not moderate lymphedema. It should be noted that while the results are

intriguing, conclusions and generalization are limited, as bandages were not worn between therapy sessions in CDT group and details about the nature of LLLT were not provided in this preliminary report.
The review by Omar et al., (24) the effect of LLLT in the management of BCRL using the volume and/or circumference of the unaffected limb to serve as a control for the affected upper limb with lymphedema showed that there is a moderate to strong evidence for the effectiveness of LLLT for the management of BCRL.

CONCLUSION:

CDT was not significantly better than LLLT in reducing volume of the affected arm in young patients with post-mastectomy BCRL nor improved the HRQL psychological score better than LLLT. It was border line better in improvement of HRQL physical & social scores. LLLT saves time & it is recommend in high workload centers

RECOMMENDATION:

1. This study highlights the need for medical and healthcare professionals to include LLLT as an effective therapeutic tool in the management young female patients with post mastectomy upper extremity lymphedema specially in the absence of too much work load. It should be considered as an alternative to CDT in centers with high work load as it is much less time consuming and more simple although it is not more effective than CDT.
2. Future further studying of combining both techniques or LLLT added to part of CDT constituents like pneumatic compression versus CDT alone is advised.

DISCLOSURE:

No conflict of interests

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