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Extracorporeal shock wave therapy versus microcurrent on pain and lymphedema post mastectomy

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ABSTRACT

Objectives: This study aimed to compare the effectiveness of extracorporeal shock wave therapy (ESWT) and microcurrent electrical nerve stimulation (MENS) in the treatment of female patients with post-mastectomy shoulder pain and lymphedema.

Methods: Thirty female patients, aged 40–65 years, with unilateral breast cancer, secondary upper limb lymphedema (stage I-II), and shoulder pain post-mastectomy were referred by oncologists from Tanta Oncology Centre, El Gharbia, Egypt. They were randomly divided into two equal groups (A and B). Group A underwent extracorporeal shock wave therapy twice weekly for four weeks, combined with traditional physical therapy, including skincare, lymphatic drainage, bandaging, and exercise. Group B received microcurrent electrical nerve stimulation for 15 minutes, three times weekly for four weeks, alongside the same traditional physical therapy. Assessments were performed before and after four weeks of treatment using the visual analogue scale (VAS) and arm volume measurements.

Findings: There was a significant decrease in the VAS in groups A and B ($p<0.05$). There was no significant post-treatment difference in the VAS assessment between both groups ($p>0.05$) When compared with its corresponding value in group B, group A presented a statistically significant decrease in the mean value of arm limb volume assessment ($p<0.05$)

Conclusions: Extracorporeal shock wave therapy (ESWT) and microcurrent electrical nerve stimulation (MENS) reduced pain in the upper limb post-mastectomy, while ESWT had more effect on reducing lymphedema of the upper limb than MENS.

KEYWORDS: Mastectomy; Lymphedema; Pain; Extracorporeal Shockwave Therapy; Microcurrent Electrical Nerve Stimulation.

1. INTRODUCTION

Mastectomy is a surgical procedure commonly performed to remove existing cancerous cells within the breast thus reducing the potential for cancer to spread [1]. Curative breast cancer surgery is divided into two types as follows: breast-conserving surgery (BCS) and modified radical mastectomy (MRM). While BCS is often the preferred option, MRM may be required. For example, if the tumor to breast ratio is unsuitable for performing BCS, a contraindication exists for radiation therapy (RT), multicentric mass occurrence, and the surgical margin cannot be provided through BCS or due to patient preference [2].

Lymphedema is a chronic disease where lymph accumulates in the limbs. Lymphedema primarily occurs due to the obstruction of the proximal lymphatic system after lymph node dissection for cancer treatment. It is a debilitating disease that can lead to swollen, heavy, painful and infection-prone limbs [3].

Breast cancer-related lymphedema (BCRL) is a major side effect of surgical treatment and radiotherapy, causing chronic lymphedema in the arm. Normal lymphatic drainage plays a key role in the elimination and transfer of waste matter (such as bilirubin and pigments) from the body and prevents swelling. Individuals with BCRL have a compromised lymphatic system which delays lymphatic drainage, causing an abnormal increase of tissue protein and resulting in chronic inflammation, fibrosis, pain, limited range of motion or paraesthesia. These symptoms can lead to functional disabilities and mental problems such as anxiety and depression [4].

According to the classification of the World Health Organization, lymphedema progresses in stages. Initially, the tissue becomes swollen in the form of non-pitting edema then, in stage 2, the affected limb becomes firm and enlarged. In stage 3, fibrosis intensifies, resulting in irreversible changes in the tissues. which is due to secondary proliferation of neutrophils, macrophages, and fibroblasts and the accumulation of collagen [5,6,7].

Complex physical therapy regimen is the most widely used treatment for lymphedema. It consists of skin care, lymphatic drainage, compression tools, and exercise to promote lymph flow. Several studies have shown that complex physical therapy may reduce the volume of lymphedema by

21%–60% [8,9]. Some common complications associated with lymphedema may include pain, swelling, restricted range of motion, development of infection, and skin sensitivity [10].

Extracorporeal shockwave therapy (ESWT) is a recently developed non-invasive treatment approach that activates vascular endothelial growth factor (VEGF) and fibroblast, thereby promoting lymphatic neovascularization. Previous studies have reported that ESWT is effective in reducing lymphedema [11,12].

Microcurrent Electrical Nerve Stimulation (MENS) applies extremely small microcurrent (less than 1 milliamperage) electrical impulses to nerves using either pads or point stimulation. Microcurrent units are engineered and built to closely approximate the body's naturally occurring bio-electric currents and produce electrical currents just above the levels of the electrical exchanges at a cellular level in the human body. The theory behind microcurrent therapy is that introducing micro impulses into the body restores the cellular balance of positive and negative electrons thus positively influencing the autonomic nervous system and accelerating the body's own healing mechanisms [13].

2. METHODS

2.1. Participants

Thirty female patients had been diagnosed clinically and referred by oncologist/physician as unilateral breast cancer with secondary upper limb lymphedema (stage I-II) and shoulder pain post mastectomy. Among them, twenty patients underwent modified radical mastectomy (MRM), while the remaining ten patients had undergone breast-conserving surgery (BCS), their ages ranged from 40 to 65 years. Patients were randomly divided into two groups with an equal number of participants. During four weeks, twice weekly (8 sessions) Group A received ESWT in addition to traditional physical therapy including exercise, bandaging, manual lymph drainage, and skin care [14]. Group B received MENS in addition to traditional physical therapy which included exercise, bandaging, manual lymph drainage, and skin care. Therapy was administered during 4 weeks, 3 sessions per week totaling 12 sessions [15].

The inclusion criteria for the study were as follows: only female patients were included, patients' age ranged between 40 to 65 years, all of them had unilateral lymphedema (stage I-II) without skin changes, and all patients enrolled had their informed consent. Exclusion criteria were as follows: Patients with evidence of local recurrence or distant metastasis, pregnant women, patients with pacemakers, recent cellulitis, venous thrombosis, and/or infection.

Before data collection, all the women who participated in this study signed an informed consent. They were advised about the nature and the effect of the treatment and measurement devices as well as instructed to report any side effects during treatment. The study consisted of thirty women from Tanta Oncology Center, El Gharbia, Egypt and was conducted from June 2021 to September 2021.

2.2. Materials

- Visual Analogue Scale (VAS) was used to assess the intensity of pain in each patient.
- Tape measurement was used to measure upper limb circumference for both sides: 5cm above the elbow, elbow level and 5cm below the elbow.
- Arm limb volume assessment was used to assess volume of lymphedema. It was done by using the formula $V = h (C2 + Cc + c2)/12 \pi$ (V: the volume of an extremity segment, C/c: circumferences at each end, π equal 3.14 and h: the distance between the ends).
- Extracorporeal shock wave therapy.
- Microcurrent electrical neuromuscular stimulation.

2.3. Procedures

Group A - Extracorporeal shock wave therapy group:

- Patients were instructed to lie in a sitting position and the affected upper limb was exposed. Skin was cleaned and gel was applied to enhance conductivity. The probe of the ESWT device was positioned at 90°angle on the upper limb.
- During each session, 1800 shocks were applied to the clinical most fibrotic zone. An additional 800 shocks were applied in a grid pattern around this area. The used frequency was 4 Hz with 2600 pulses per session, at an energy level of 0.10 mJ/mm2 [14].
- Any side effects from the ESWT procedure were recorded during treatment. All patients were recommended to follow a daily home routine of skin care, to avoid sleeping on the affected side, to elevate the affected upper extremity, and an active range of motion exercises.
- Treatment was performed twice a week during four weeks.

Group B - Microcurrent electrical neuromuscular stimulation (MENS) group:

- Patients were instructed to lie in a sitting position, the affected upper limb was exposed, and skin was cleaned to apply the adhesive pads.
- The first pair of adhesive pads was placed on the tip of shoulder and the second pair at the wrist level.
- The applied intensity was set at 25 mA, and pulsation frequency at 5 pps; each session lasted 15 minutes [16].
- Any side effects from MENS were recorded during treatment procedures. All patients were recommended to follow a daily home routine of skin care, to avoid sleeping on the affected side, to keep the affected upper extremity elevated, and an active range of motion exercises.
- Treatment was performed in three weekly sessions for four weeks.

2.4. Statistical analysis

Descriptive statistics and unpaired t-tests were conducted for age comparison between groups. Normal distribution of data was checked using the Shapiro-Wilk test for all variables. Levene's test for homogeneity of variances was conducted to check the homogeneity between groups. Unpaired t-tests were conducted to compare the mean values of VAS, lymphedema size, and volume between groups A and B. Paired t-tests were conducted to compare between groups pre and post-treatment. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

3. RESULTS

3.1 Subject characteristics

The mean ± SD age of group A was 50.06 ± 6.72 years, with a maximum value of 65 years and a minimum value of 40 years. The mean ± SD age of group B was 51.13 ± 6.68 years, with a maximum value of 65 years and a minimum value of 40 years. There was no significant difference between both groups in the mean age values ($p = 0.66$).

3.2. Effect of treatment on pain

Within group comparison

There was a significant decrease in VAS scores after treatment in both groups A and B compared to pre-treatment (p < 0.001). The percent of decrease in VAS was 63.83% in group A and 60.53% for group B. (Table 1).

Table 1. Mean VAS pre and post treatment of the group A and B

	Group A	Group B			
	Mean ± SD	**Mean ± SD**	**MD**	**t value**	**p value**
VAS					
Pre treatment	8.46 ± 1.3	8.26 ± 1.22	0.2	0.43	0.66
Post treatment	3.06 ± 1.09	3.26 ± 1.27	-0.2	-0.45	0.65
MD	5.4	5			
% of change	63.83	60.53			
t- value	22.97	38.22			
	p = 0.001	*p = 0.001*			

Comparison between groups

There was no significant difference between groups pre-treatment (p > 0.05). Comparison between groups A and B post-treatment revealed a non-significant difference in VAS (p > 0.05).

3.3. Effect of treatment on lymphedema size and volume

Within group comparison

Compared with pre-treatment measures (p > 0.001), the size of lymphedema decreased significantly post-treatment in groups A and B. The percentage of decrease in the size of lymphedema 5cm above the elbow, at elbow level, and 5 cm below the elbow in group A was: 18.69, 20.68, and 23.82 respectively while measurements in group B were: 4.9, 3.76, and 5.05% respectively.

There was a significant decrease in lymphedema volume post-treatment in group A and B compared with that of pre-treatment (p < 0.001). The percentage of decrease in lymphedema volume in group A was 37.55% and 9.57%. for group B (Table 2).

Between group comparison

There was a significant decrease of lymphedema size and volume in group A compared with that of group B (p < 0.01) (Tables 1-2, Figures 1-2).

Table 2. Mean lymphedema size and volume pre and post treatment of the group A and B

	Group A	Group B			
	Mean ± SD	Mean ± SD	MD	t- value	p value
Lymphedema size (cm)					
Above elbow 5 cm					
Pre treatment	36.06 ± 3.1	34.07 ± 3.77	2	1.58	0.12
Post treatment	29.32 ± 3.31	32.4 ± 3.47	-3.08	-2.48	0.01
MD	6.74	1.67			
% of change	18.69	4.9			
t- value	19.56	7.17			
	p = 0.001	***p = 0.001***			
Elbow level					
Pre treatment	33.07 ± 3.17	31.13 ± 3.33	1.94	1.62	0.11
Post treatment	26.23 ± 3.59	29.96 ± 2.91	-3.73	-3.12	0.004
MD	6.84	1.17			
% of change	20.68	3.76			
t- value	35.38	4.24			
	p = 0.001	***p = 0.001***			
Below elbow 5 cm					
Pre treatment	32.33 ± 3.96	30.1 ± 3.44	2.23	1.64	0.11
Post treatment	24.63 ± 4.06	28.58 ± 3.64	-3.95	-2.8	0.009
MD	7.7	1.52			
% of change	23.82	5.05			
t- value	24.12	4.23			
	p = 0.001	***p = 0.001***			
Lymphedema volume (ml)					
Pre treatment	461.82 ± 70.95	412.92 ± 95.88	48.9	1.58	0.12
Post treatment	288.39 ± 65.35	373.41 ± 80.68	-85.02	-3.17	0.004
MD	173.43	39.51			
% of change	37.55	9.57			
t- value	35.76	7.73			
	p = 0.001	***p = 0.001***			

**SD, standard deviation; MD, mean difference; p-value, probability value*

Figure 1. Group A, ESWT, pre and post-treatment

Figure 2. Group B, MENS, pre and post-treatment

4. DISCUSSION

The results of this study support that both, post-mastectomy extracorporeal shock wave therapy and microcurrent reduced pain of the upper limb however, ESWT had more effect on reducing lymphedema than microcurrent. The findings of this study are broadly consistent with the major trends observed by Rompe et al. [17] who stated that shock waves induced an analgesic effect in the treatment of calcifying tendonitis of the shoulder by overstimulating the axons, thereby increasing pain threshold.

Also, the work of Malay et al. [18] mentioned that shock waves include the physical alteration of small axons, inhibiting pain impulse conduction and chemical alteration of pain receptors and neurotransmitters, as well as preventing pain perception.

Cho et al. [19] related that, when lateral epicondylitis patients were treated by ESWT, the patient's pain decreased significantly and muscle strength increased significantly.

Schmitz and DePace, [20] attributed to the effect of ESWT that, cause reduction of substance P in the target tissue in conjunction with reduced synthesis of this molecule in dorsal root ganglia cells as well as by selective destruction of unmyelinated nerve fibers within the focal zone of ESWT.

In another study, Kubo et al. [11] compared low-energy ESWT with untreated controls in a rabbit ear model of lymphoma. A marked reduction in the thickness of lymphoedematous ears and a significantly increased expression of VEGF receptor 3 in lymphatic vessels were observed in the ESWT-treated group.

Likewise, Na, [21] reported that when ESWT was used to treat chronic low back pain, patients' pain significant decreased. Bae and Kim, [22] who investigated the effectiveness of ESWT treatment in 7 patients with lymphedema secondary to breast cancer and reported statistically significant reductions in volumetric and circumferential measurements and VAS scores of patients following treatment. Lee et al. [23] discovered that chronic low back pain patients who were treated with an exercise program and ESWT experienced reduced pain and improved dynamic balancing, compared to those who were treated with an exercise program and conservative physical therapy.

Park et al. [24] showed that the extracorporeal shock wave therapy group showed significantly lower scores of terms of visual analog scales and patient-specific functional scales than the conservative physical therapy group. Cebicci et al. [25] examined the effectiveness of ESWT in the treatment of lymphedema, 11 patients received ESWT alone which was found to reduce lymphedema with sustained efficacy over 6 months. Cebicci and Dizdar, [26] found that complex decongestive therapy and extracorporeal shock wave therapy resulted in reduced lymphedema volume and improvement in upper limb function of patients with lymphedema secondary to breast cancer. Complex decongestive therapy is a costly treatment strategy that requires a multidisciplinary approach. On the other hand, extracorporeal shock wave therapy is a promising novel and non-invasive treatment modality which is convenient and effective.

In study of Lee et al. [27] it was found that a substance produced by pain was removed by the local blood flow stimulated by the stimulation. Therefore, pain relief occurs when the rate of tissue healing increases because of the blood flow, causing removal of the substances causing pain (substance P).

Chung and Cho, [28] who also found that microcurrent stimulation was very effective at significantly relieving pain in patients with degenerative knee arthritis. Chevalier et al. [29] found that the results obtained in group A can be attributed to microcurrent mimicking human bio-cellular communications that regulate the autonomic nervous system, which results in body-wide therapeutic benefits. Furthermore, Labib et al. [30] claimed that the application of MENS had a valuable effect on post-mastectomy shoulder pain lymphedema as evidenced by the highl

Wahaj et al. [31] conducted clinical studies that showed that microcurrent stimulation was highly effective at alleviating the pain of the temporomandibular joint showing significant decrease in VAS and VLM.

Saranya et al. [32] said that MENS is a form of electrotherapy current that provides subthreshold or sub-minimal stimulation lower than 1000 microamps (μA). MENS works on the principle of Arndt–Schulz law. It is theorized that healthy tissue is the result of the direct flow of electric current throughout our body. Electrical balance is disrupted when the body is injured at a particular site, causing the electric current to change course. The use of microcurrent over the injured site is thought to realign this flow, thus aiding in tissue repair. Maul et al. [33] reported that microcurrent stimulation in 72 patients with facial pain due to sinus disease showed a reduction in their mean VAS score from 5.63 cm before treatment to 3.97 cm after treatment.

According to Yi et al. [15] microcurrent stimulation is based on bioelectrical theory and cell communication theory, stating that it is affected by a specific signal transduction system between cells through intracellular ion channels and has excellent stability and few side effects. He also found that, after four weeks of treatment with microcurrent stimulation ($p < 0.05$), pain was significantly reduced in the experimental group compared with the control group.

5. CONCLUSIONS

In conclusion, the findings of this study suggest that both extracorporeal shock wave therapy (ESWT) and microcurrent stimulation (MENS), when added to traditional physical therapy, were effective and safe in reducing pain and lymphedema following mastectomy. However, ESWT showed greater effectiveness than MENS in reducing the size of lymphedema in the upper limb.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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