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# Effects of Electrohydraulic Therapy of Shock Waves on Pain and Lymphedema Measurement Post-Radical Mastectomy

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## ABSTRACT

***Background:*** Lymphedema post-mastectomy remains a challenging problem. This study aimed to investigate the efficacy of shock wave electrohydraulic treatment (ESWT) for patients with pain and lymphedema.

***Methods:*** Thirty patients (30 women) with pain & lymphedema post-radical mastectomy were evaluated to participate in this Clinical trial. They were recruited from the Minia Cancer Institute- Minia University and Deraya University outpatient clinics. Their ages varied between the ages of 40 and 50 years. They were divided into two groups. Group (1) 'Group of studies': 15 patients seeking ESWT in addition to conventional medical care. Group (2) 'Control group': 15 people seeking conventional medical care only. Patients of the study group (1) were treated with a number of impulses, at least 500 shocks at E2 at 4Hz (equivalent to 0.11mJ/mm square energy). Treatment sessions were delivered twice weekly for six treatments (3 weeks). The assessment used a Visual analogue scale (VAS) for pain and arm circumference midway between the shoulder and elbow for lymphedema measurement.

***Results:*** showed that (ESWT) on pain and lymphedema measurement post-radical mastectomy effectively decreased pain as evidenced by the highly significant decreases in the visual analogue scale. These results revealed a substantial VAS reduction (P<0.0001). Effects of the ESWT on lymphedema measurement via the arm circumference measurement at the point where the shoulder and the elbow meet post-radical mastectomy were investigated. These results revealed a notable reduction in the mean value of the arm circumference measurement (ACM) (P<0.0001).

***Conclusion:*** The significant reductions in VAS and assessment of the ACM arm range show that the ESWT, in addition to conventional therapy, significantly impacted upper limb structural components following radical mastectomy.

***Keywords:*** Shock waves, ESWT, Pain, Lymphedema, Arm circumference, Quality of life, Visual analogue scale.

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## INTRODUCTION

An anomaly or injury to the lymphatic system brings on long-lasting and persistent illness of lymphedema. An uneven increase in tissue proteins, edema, systemic inflammation, and fibrosis characterizes this. In addition, many factors, including lymphatic stasis with inflammation, lymph node dissection, radiation, and trauma, may bring on secondary lymphedema [1,4].

An obstruction in the lymphatic drainage system causes lymphedema, the accumulation of protein-rich fluid in the soft tissues. The extremities are the most specific areas it affects; however, it can also affect the brain, spine, liver, lungs, and genital region. Lymphedema can be of two different forms. Primary lymphedema can develop in babies (congenital), teens (praecox), or individuals beyond the age of 35 and is brought on by lymphatic system growth abnormalities. Secondary lymphedema is the most prevalent kind of lymphedema. This typically happens following oncology surgery or radiation therapy. The condition may also be brought on by radiation-induced alterations in the basal epidermal tissues, lymphatic system destruction from metastatic disease, or surgical excision of some or all lymphatic nodal reservoirs [2].

A chronic condition known as lymphedema is brought on by a substantial accumulation of protein-rich fluid in the interstitial space due to inadequate lymphatic drainage. Swelling, fibrosis, and hardness of the afflicted tissues are medical symptoms that cause itchiness, pain, and restricted joint mobility. In addition, the sluggish, protein-rich environment encourages the growth of germs, increasing the likelihood of an infection. Estimates range from 6% to 83% for the incidence of breast cancer linked to lymphedema. Edematous parts can happen and have been associated with a variety of factors, including trauma to the lymphatic system, cut in an earlier surgically treated arm, the growing size of the post-treatment tissue, axillary nudity status, the number of axillary knots extracted, surgical approach, and age [1].

A long-lasting sign of edema and persistent inflammation brought on by lymphedema's high protein accumulation in tissue is the loss of muscular flexibility, which limits the range of motion. With therapies that require radiotherapy to the armpit, patients cured of breast cancer might be left with a life-long legacy of arm swelling. This is believed to be due to the narrowing of lymphatic channels that pump tissue fluid out of the arm rather than blood draining through veins. This complication has been considered radical and permanent over several decades [2].

## MATERIAL AND METHODS

Subjects: Thirty female patients who recently had a mastectomy two months before participating in the study and were experiencing shoulder discomfort and arm lymphedema. The patients were recruited from The National Cancer Institute. They ranged in age from forty to fifty. Group (1) "Study group": Fifteen patients who received (ESWT) in addition to conventional medical care. Group (2) "Control group": Fifteen patients received only the traditional medical treatment. Patients of the study group (1) were treated with the shock wave source that will be used, the Derma Pace System for the electrohydraulic therapy of shock waves (ESWT): Number of impulses at least 500 shocks at E2 at 4Hz (equivalent to 0.11mJ/mm square energy flux density) will be delivered twice weekly for a total six treatments (3 weeks) [7].

**I. Exclusive criteria**

The participants were excluded if they met one of the following criteria:

- Patients with a UL diameter disparity greater than two centimeters before the operation.
- Patients who had a UL ipsilateral surgery infection.
- Patients who received radiation therapy.
- Patients who do not grasp the suggested exercises [14].

**II. Inclusive criteria**

The patient's selection was according to the following criteria:

- Age ranged between 40 - 50 years.
- Only females participated in the study.
- All patients recently had a mastectomy two months before participating in the study.
- All patients were experiencing shoulder discomfort and arm lymphedema [14].

**Instrumentation:**

Derma Pace System for the electrohydraulic therapy of shock waves (ESWT) Sanuwave Health Inc., of Alpharetta, **Georgia:**

This method generates extremely energetic impulses using a portable probe. According to the apparatus manufacturer, the system enhances angiogenesis, biofilm disruption, perfusion, arteriole-genesis, and factor of development after triggering, which reduces discomfort and lymphedema and aids in the reconstruction of the skin, musculoskeletal, and blood vessel tissues. Several impulses in the treatment of at least 500 shocks at E2 at 4Hz (equivalent to 0.11mJ/mm square energy flux density) will be delivered twice weekly for a total of 6 treatments (3 weeks) [7].

**Measurement equipment and tools:**

**Visual Analogue Scale (VAS):** A visual analogue scale was used to gauge the pain level. The VAS is a fixed ten-centimeter line with zones at either end, such as the greatest potential pain and no discomfort [6].

**Tape measure:** Using a measuring tape to determine the diameter of your arm where the elbow and shoulder meet. The arm's circumference was measured before treatment began (1st record) and again three weeks later, at the end of the session (2nd record) [11].

**Treatment:**

Patients in the two groups (A and B) get the same conventional treatment, nursing support, and nutrition as specified. The ESWT, a portable sensor, provides high-energy impulses while the patient is seated with back

support. A number of impulses in treatment at least 500 shocks at E2 at 4Hz (equivalent to 0.11mJ/mm square energy flux density) will be delivered midway over the arm midway between shoulder and elbow twice weekly for a total of 6 treatments (3 weeks) [3].

**Data analysis:**

(VAS) and arm diameter records were evaluated in the two groups both before and after the end of the therapeutic program. Data were entered into a computer for statistical analysis, and descriptive stats were computed for each group as the medium, standard deviation, minimum, and maximum. A threshold of significance of 0.05 was applied. Mann- Whitney and student t-tests were employed to analyze the connection between shoulder discomfort and existing lymphedema. An ANOVA was performed to assess shoulder pain and lymphedema throughout the follow-up with repeated measurements. The tools utilized for the study (R Project) were the R Environment for statistical computation [13].

## RESULTS

Table 1: Thirty female patients suffering from shoulder annoyance and arm lymphedema after mastectomy were recruited from the National Cancer Institute. They were between the ages of 40 and 50.

**Table 1: Demographic characteristics and measurement data of all participants.**

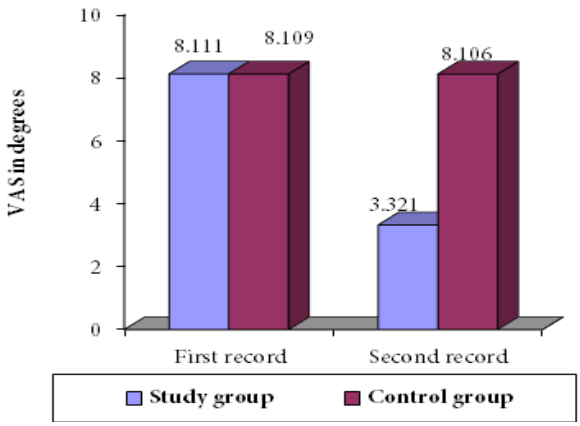
| | Cases (n = 15) | | Controls (n = 15) | |
|---|---|---|---|---|
| | n | % | N | % |
| **Age** | | | | |
| 40-45 years | 9 | 60 | 4 | 26.6 |
| 45-50 years | 2 | 13.3 | 7 | 46.6 |
| 50-55 years | 4 | 26.6 | 4 | 26.6 |
| **Area of residence** | | | | |
| Cairo region | 6 | 40 | 5 | 33.3 |
| Upper Egypt | 8 | 53.3 | 10 | 66.6 |
| Missing or unspecified | 1 | 6.6 | 0 | 0 |
| **Level of education** | | | | |
| Less than secondary | 1 | 6.6 | 1 | 6.6 |
| Secondary | 2 | 13.3 | 1 | 6.6 |
| Tertiary | 12 | 80 | 13 | 86.6 |
| **Working status** | | | | |
| Worker | 8 | 53.3 | 2 | 13.3 |
| House wives | 5 | 33.3 | 9 | 60 |
| self-employed | 2 | 13.3 | 4 | 26.6 |
| **Marital status** | | | | |
| Single | 12 | 80 | 13 | 86.6 |
| Married | 3 | 20 | 2 | 13.3 |
| **Operated breast** | | | | |
| Right | 9 | 60 | 7 | 46.6 |
| Left | 6 | 40 | 8 | 53.3 |
| **Smoking** | | | | |
| Yes | 11 | 73.3 | 8 | 53.3 |
| No | 4 | 26.6 | 7 | 46.6 |
| **Heaviness sensation** | | | | |
| Yes | 9 | 60 | 11 | 73.3 |
| No | 6 | 40 | 4 | 26.6 |
| **Practice of exercises** | | | | |
| Yes | 13 | 86.6 | 9 | 60 |
| No | 2 | 13.3 | 6 | 40 |

The present study investigated the effects of ESWT on pain and lymphedema of the upper limb post-radical mastectomy. As shown by Table (1) and Figure (1), in the study group, the mean value on the VAS scale was (8.111±0.131), while (3.321±0.222) was (3.222) graded after therapy). These findings show that the VAS (P<0.0001) was very important. In the control group, however, the mean value of the VAS was (8.109 ±0.111) grades, and it was (8.106 ±0.108) degrees, which revealed a non-great difference in VAS after the treatment (P > o. o5).

**Table 2: Comparison of both classes' average value, pre and post-treatment VAS values.**

| | Before treatment | | After treatment | | Mean Difference | T. value | P. value |
|---|---|---|---|---|---|---|---|
| | Mean in degrees | ± SD | Mean in degrees | ± SD | | | |
| Study group | 8.111 | 0.131 | 3.321 | 0.222 | 4.79000 | 71.97 | < 0.0001 |
| Control group | 8.109 | 0.111 | 8.106 | 0.108 | 0.003000 | 0.08 | 0.941 |

**Figure 1: Mean rank VAS values before and after therapy in both classes.**



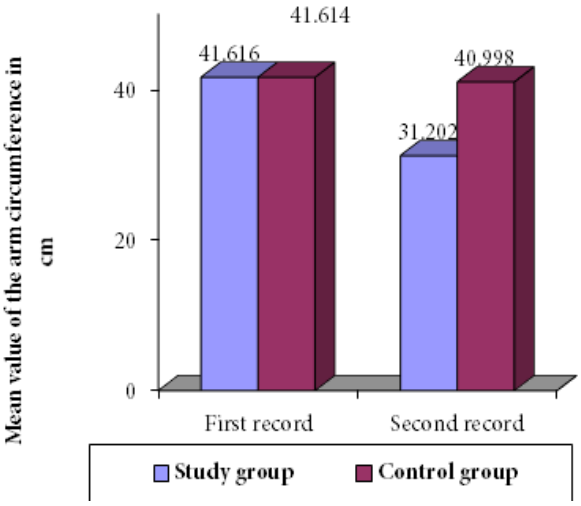

In the current study, lymphedema following radical mastectomy was measured using the arm circumference at the place where the shoulder and elbow connect. As can be observed in Table (2) and Figure (2), the sample population's mean arm circumferential measurement (ACM) value before treatment was (41.616 6.515) cm, whereas it was (31.202 5.727) cm after therapy. This result demonstrated a substantially lower mean arm diameter (ACM) measurement (P0.0001). (ACM) and following treatment (40.998 6.510). This demonstrated that there was no significant difference in the mean arm circumference measurement (ACM) (P > o. o5). However, the mean measurement for arm circumference (ACM) in the test

group was 41.614 6.513; after therapy, it was 40.998 6.510. This demonstrated that there was no significant difference in the mean arm circumferential measurement (ACM) (P > o. o5).

**Table 3: Analysis of the arm circumference calculation (ACM) mean values of all classes before and during therapy.**

| | Prior to treatment | | Following treatment | | Mean difference | T. value | P.value |
|---|---|---|---|---|---|---|---|
| | Mean in Percentage scores | ± SD | Mean In percentage scores | ± SD | | | |
| Study group | 41.616 | 6.515 | 31.202 | 5.727 | 10.4140 | 4.65 | < 0.0001 |
| Control group | 41.614 | 6.513 | 40.998 | 6.510 | 0.61600 | 0.26 | 0.798 |

**Figure 2: Mean arm circumference measurement (ACM) values in cm for all classes, before and after therapy.**




## DISCUSSION

This study investigated the efficacy of shock wave electrohydraulic treatment (ESWT) for patients with pain and lymphedema.

According to the current study (ESWT) results on pain and lymphedema, assessment following radical mastectomy helped reduce pain, as shown by the extremely substantial reductions in the visual analogue scale. In addition, these findings demonstrated a significant VAS decrease (P 0.0001). After a radical mastectomy, the effects of the ESWT on lymphedema by measuring the arm circumference at the site where the shoulder and elbow meet were examined. These findings demonstrated a significant decrease in the arm circumferential measurement's (ACM) mean value (p 0.0001).

Maier et al., 2000 stated that ESWT may be suggested as an additional therapy. Patients in his research who had breast cancer-related stage 3 lymphedema received ESWT. The VAS score, volume, circumference, and skin thickness changed significantly following therapy [9].

The results of this study are in accordance with Chen H.S. et al., 2001 who revealed Breast cancer-related lymphedema patients utilizing ESWT experienced notable improvements in volume, QuickDASH, and the condensed version of the World Health Organization Quality of Life. The potential of ESWT to boost VEGF synthesis is essential for promoting lymphangiogenesis and lowering lymphedema [12].

Hammer et al., 2002 agree with that hypothesis and suggest that his study measured skin thickness as well, and the results showed that individuals with lymphedema from breast cancer had less fibrotic skin changes. Untreated lymph accumulation causes lymphostatic fibrosis, which worsens the condition of the edema. As a result, fibrosis worsens as the lymphedema stage increases. According to studies that employed ESWT on individuals with sclerosis, it may be an effective therapy for those with skin fibrosis [5].

The results of this study were in accordance with Weil et al., 2002 who stated that 72 patients with primary (25) or secondary (47) lymphedema of the upper and lower limbs underwent ten sessions of shockwave treatment. Patients conducted assessments at two and one-month intervals following treatment. The limb's size is frequently reduced by 26%, and the tissue's consistency is subjectively and objectively diminished, especially in fibrotic regions. Therefore, in addition to lowering limb volume, shock wave treatment is beneficial for treating the fibrotic regions of primary and secondary lymphedema [8].

Ogden et al., 2001 stated that lymphedema was treated using shockwave treatment, which resulted in a 32% reduction in the average circumference of the afflicted limb. Additionally, tissue consistency decreased subjectively and objectively, especially in the associated fibrotic regions [10].

Gaskin TA, 2004 stated that an evaluation of the effectiveness of ESWT as a therapeutic technique for the management of stage 3 secondary lymphedema was done in a pilot trial on seven patients using clinical criteria such as the volume and circumference of the upper limb and skin fold thickness. All patients had shockwave treatment four times, and the overall volume decrease (37.23%) was impressive [15].

Finally, after discussion of the findings and reports in fields similar to this analysis from the previous investigators, in comparison to conventional therapy, the application of ESWT had a beneficial impact on the functional operation of the post-mastectomy upper limb, as shown by the significant decreases in VAS and the very significant decreases in the calculation of ACM arm circumference [14].

The most significant reductions in pain and lymphedema have had a valuable effect on functionality through the research with the implementation of ESWT [4].

Patients will benefit even more if they use an aggressive approach to follow physical therapy guidelines such as

manual lymphatic drainage(MLD), which is a healthy and efficient exercise in post-breast cancer surgery recovery [15].

If health conditions need to be improved, aggressive active therapeutic delivery methods are not recommended [7].

There were limitations in the study, like the small sample size, using only two assessment techniques, and the short-term effects of ESWT.

In future studies in the same scope, we recommend using larger sample size, different subjective and objective assessment methods, and combining ESWT with other innovative ways of treating lymphedema.

## CONCLUSION

The evident differences in VAS and the highly significant decreases in the calculated value of the ACM arm range demonstrate that the ESWT, in addition to the conventional therapy, had a positive impact on the functional activity of the upper limb following radical mastectomy.

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