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ORIGINAL RESEARCH

Extracorporeal Shock Wave Therapy for Breast Cancer—Related Lymphedema: A Pilot Study

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Abstract

Objective: To investigate the clinical effect of extracorporeal shock wave therapy (ESWT) in patients with secondary lymphedema after breast cancer treatment.

Design: Prospective clinical pilot study.

Setting: Education and research hospital.

Participants: Women with a diagnosis of lymphedema secondary to breast cancer (N = 11).

Interventions: Patients were treated for 12 sessions of ESWT with 2500 impulses each. The treatment frequency was 4Hz in multiple shock mode. The energy flow density during treatment was equal to a working pressure of 2 bar.

Main Outcome Measures: The primary outcome measure was volumetric measurements. The secondary outcome measures were the short version of the Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) and the brief version of the World Health Organization Quality of Life (WHOQOL-BREF). Assessments were conducted by the same investigator at baseline, posttreatment, and at 1, 3, and 6 months after treatment for all patients.

Results: Significant reduction was found in the amount of lymphedema with ESWT treatment in all patients, and this reduction was maintained for 6 months. A statistically significant reduction was observed in volumetric measurements for the follow-up period ($P = .001$). The mean volume displacement of the affected upper extremity before treatment was 870.45±384.19mL at 6 months, and after the treatment it was 604.54±381.74mL. In addition, improvements were observed in the QuickDASH functional assessment tool and in the physical health domain of the WHOQOL-BREF questionnaire ($P = .002$ and $P = .007$, respectively).

Conclusions: ESWT was shown to provide a reduction in the amount of lymphedema in patients with lymphedema secondary to breast cancer. Also, a marked improvement was observed in the functional status and quality of life of study patients. Treatment efficacy was maintained in the long term. As a noninvasive, novel, and effective method, ESWT is a promising treatment modality for the treatment of lymphedema, which is a chronic, progressive, and refractory condition.

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Lymphedema is the accumulation of protein-rich interstitial fluid in tissues caused by insufficiency of the lymphatic system.[1-3] Primary lymphedema occurs as a result of a congenital anomaly of lymphatic vessels. Secondary lymphedema develops after resection or obstruction of lymphatic vessels or lymph nodes.[2,3] Secondary lymphedema may also develop as a major complication of cancer surgery or radiotherapy.[1-3]

One of the most important complications of breast cancer treatment is the development of lymphedema in an upper extremity.[2,3] Patients with breast cancer are at increased risk for lymphedema after axillary lymph node dissection and radiotherapy.[1,2] The incidence of breast cancer—related lymphedema is reported at 6% to 30%.[3,4]

Lymphedema is a chronic and progressive condition that is refractory to treatment.[3,5] It causes swelling, pain, limitation of movement, susceptibility to infection in the extremities, and sensitivity of the skin.[1,4,5] Because there is no cure for lymphedema, the aim of treatment is to reduce the swelling, increase joint mobility, and

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decrease discomfort.[2] One of the most common forms of lymphedema treatment is complex decongestive therapy (CDT). CDT includes the application of low-stretch bandaging, manual lymph drainage, compression therapy, exercise, and skin care.[5-8] Reviews consistently concluded that CDT is an effective therapy for lymphedema.[7,9] Although CDT benefits most patients with lymphedema, the interventions are labor-intensive, time-consuming, and expensive. The potentially uncomfortable and visible garments may adversely affect the patient's quality of life (QOL).[10]

There are some studies investigating the use of alternative treatment methods (eg, laser therapy, acupuncture, kinesio taping) for the treatment of lymphedema.[11-14] These treatments have yielded mixed results. In some studies, low-level laser therapy was found to help reduce the swelling in the arm, break down scar tissue, and increase range of motion.[11,12] Early clinical trials have shown that acupuncture can decrease limb swelling and improve the symptoms of lymphedema in both the lower and upper extremities.[13] In a pilot study, kinesio taping appeared to be ineffective at breast cancer–related lymphedema.[14]

For many years, extracorporeal shock wave therapy (ESWT) has been used for various musculoskeletal system disorders, including plantar fasciitis, lateral epicondylitis, and shoulder tendinitis.[15,16] ESWT induces neovascularization by stimulating the release of angiogenic growth factors from cells (eg, nitric oxide, vascular endothelial growth factor [VEGF], bone morphogenetic protein). Because of this mechanism of action, several new areas have emerged for ESWT use, including treatment of spasticity, chronic skin ulcers, burn scars, avascular necrosis, and myocardial ischemia.[17,18]

Animal studies have found that ESWT stimulates lymphangiogenesis and reduces lymphedema by inducing increased release of the VEGF.[1,15] In 1 study, low-energy shock wave therapy induced therapeutic lymphangiogenesis by upregulating VEGF-C (a protein that is a member of the VEGF family) and basic fibroblast growth factor and improved lymphedema in a rat tail model.[1] In another study, low-energy ESWT was used for the treatment of lymphedema in a rabbit ear model; compared with the nontreated group, the treated group showed a marked reduction of lymphedema and a significant upregulation of VEGF receptor 3 in the lymphatic vessels.[15]

Only 1 study was available in the literature that examined the effectiveness of ESWT for the treatment of breast cancer–related lymphedema. In that study, although ESWT was found to be effective in reducing lymphedema, its long-term effectiveness was not investigated.[16]

Breast cancer–related lymphedema significantly compromise QOL. Physical arm morbidities caused by lymphedema can lead to negative feelings, particularly regarding one's body image. Patients with lymphedema have been shown to experience stress, anxiety, sadness, anger, and guilt because of their condition. QOL and improved function are 2 important results of treatment, but they were examined in only a few studies.[19,20]

List of abbreviations:

CDT	**complex decongestive therapy**
ESWT	**extracorporeal shock wave therapy**
QOL	**quality of life**
QuickDASH	**short version of the Disabilities of the Arm, Shoulder and Hand Questionnaire**
VEGF	**vascular endothelial growth factor**
WHOQOL-BREF	**brief version of the World Health Organization Quality of Life**

In this study, we aimed to examine the long-term effectiveness of ESWT in breast cancer–related lymphedema. Additionally, we evaluated the QOL and functional status of the patients.

Methods

Participants

This prospective clinical pilot study was conducted in women in the medical oncology department with a confirmed diagnosis of breast cancer and clinical manifestations of lymphedema. Ethical approval for the conduct of the study (no. 2014/44) was granted by the Erciyes University Ethical Committee for Clinical Trials, and informed consent was obtained from each subject.

The patients were included if they had completed their chemotherapy or radiotherapy treatments within no more than 6 months and had a volume difference >200mL and a circumference difference >2cm between their 2 arms. Patients with the following characteristics were excluded from the study: those with bilateral breast cancer, those with bilateral lymphedema, those with metastasis, those with acute deep vein thrombosis, those suffering from acute or untreated infections on the affected arm, and those who had undergone any lymphedema treatment within a 6-month period.

Interventions

Patients received a total of 12 sessions of ESWT 3 times per week. A Vibrolith Ortho[a] ESWT device was used. ESWT was applied using the same parameters for all patients: 2500 shocks per session with a frequency of 4Hz at 2 bars of pressure.[18] Patients were placed in a supine position on the examination table. During treatment, a 15-mm head was used without local anesthesia. Then 750 shocks were applied to the axillary lymph nodes and 250 shocks were applied to the cubital lymph nodes. The remaining 1500 shocks were applied to the arm, forearm, and hand. All patients were treated by the same physical therapist at each session.

Primary outcome measurements

Volumetric measurements

For lymphedema follow-up, the volumetric measurement method is accepted as the criterion standard.[5,21,22] In this method, the patient's arm is immersed into a cylindrical container filled with water, and the volume of the overflowed water is measured in milliliters. The difference of the overflowing water volume of the 2 extremities determines the amount of lymphedema.[5,6,16]

In this study, the patient's extremity was immersed in a cylindrical container filled with water up to the axilla level, with the arm and forearm in the extension position and the fingers in the abduction position before the volume of the displaced water was measured. The volume displacement between the unaffected arm and the arm with lymphedema was determined.

For all patients, the intensity of lymphedema was assessed using Tracey volume category.[23] As such, a volume difference of 150 to 400mL between the 2 upper extremities was considered mild, 400 to 700mL was considered moderate, and ≥700mL was considered to be severe lymphedema.

Secondary outcome measurements

Short version of the Disabilities of the Arm, Shoulder and Hand Questionnaire

The short version of the Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) was used for assessment of the functional status of the patients. The QuickDASH is a self-report questionnaire designed to measure physical function and symptoms in people with a musculoskeletal disorder of the upper limb. In addition to checking physical functional disabilities, this questionnaire tests the presence of pain, muscle weakness, numbness, level of difficulty in performing activities of daily living, and also criteria related to work and leisure. A higher scores indicates a greater level of disability and severity, whereas a lower score indicates a lower level of disability. The score ranges from 0 (no disability) to 100 (most severe disability).[22]

Brief version of the World Health Organization Quality of Life

The brief version of the World Health Organization Quality of Life (WHOQOL-BREF) was used to evaluate the affect of disease on life satisfaction. The WHOQOL-BREF instrument consists of 26 items that measure the following domains: physical health (7 items), psychological health (6 items), social relations (3 items), and environment (8 items). Two other items measure overall QOL and general health. Items are rated on a 5-point Likert scale (low score of 1 to high score of 5) to determine a raw item score. Subsequently, the mean score for each domain is calculated, resulting in a mean score per domain that falls between 4 and 20, with a higher score indicating a higher QOL.[24] The reliability and validity of a Turkish version were demonstrated by Eser et al.[25]

Assessments

Assessments were conducted by the same investigator at baseline, posttreatment, and 1, 3, and 6 months after treatment for all patients.

Statistical analysis

SPSS for Windows 21[b] was used for all statistical analyses. Means and SDs and median (minimum−maximum) values were estimated for all data. Demographic characteristics were reported using descriptive statistics. Multivariate repeated measures were used to test the significance of differences in volumetric measurements and WHOQOL-BREF and QuickDASH scores at baseline, posttreatment, and 1, 3, and 6 months after treatment. Cohen *d* effect size, calculated as the difference between treatment periods, divided by the SD of these data sets, was used for volumetric measurements. Effect sizes <0.2 were considered small, effect sizes of 0.5 were considered moderate, and effect sizes >0.8 were considered large.

Results

This study enrolled 73 patients who were admitted to the medical oncology department with breast cancer−related lymphedema between February 2014 and August 2014. Excluded from the study were 38 patients who had metastasis, 5 patients who had bilateral breast cancer, 12 patients who had undergone lymphedema treatment within a 6-month period, and 3 patients who had untreated infections on the affected arm. Four patients refused to participate. A total of 11 patients were ultimately recruited. The flowchart of patient recruitment is shown in figure 1.

The mean age ± SD of the patients was 50.63±7.03 years. The duration of lymphedema was ≤1 year in 6 patients and ≥1 year in 5 patients. All patients were women who had undergone modified radical mastectomy; 8 had concomitant radiotherapy.

Among the 11 patients, lymphedema was mild in 1, moderate in 2, and severe in 8. After 6 months of treatment, 3 patients had mild lymphedema, 5 had moderate lymphedema, and 3 had severe lymphedema.

Mild ecchymosis and pain may occur as side effects of ESWT treatment. No problems were reported after ESWT application in our patients, except transient skin redness that occurred in 2 patients.

Demographic and disease-related characteristics are shown in table 1.

We found a significant reduction in the amount of lymphedema with ESWT treatment in all patients, and this reduction was maintained for 6 months. A statistically significant reduction was observed in volumetric measurements at posttreatment and 1, 3, and 6 months after treatment versus baseline ($P=.001$, $P=.001$, $P=.001$, and $P=.001$, respectively). Another statistically significant reduction was observed in volumetric measurements at 1, 3, and 6 months after treatment versus posttreatment ($P=.02$, $P=.002$, and $P=.001$, respectively). The mean differences of volumetric measurements for the follow-up period are shown in table 2. The effect size for volumetric measurements in comparison with baseline ranged from 0.3 to 0.6. The effect sizes for volumetric measurements for the follow-up period are given in table 2. The mean volume displacement before treatment was 870.45±115.10mL; after 6 months of treatment it was 604.54±115.10mL. The mean volume displacements for the follow-up period are shown in figure 2.

A statistically significant improvement was observed in the QuickDASH functional assessment scores at posttreatment and 1, 3, and 6 months after treatment versus baseline ($P=.005$, $P=.001$, $P=.001$, and $P=.001$, respectively). Another statistically significant improvement was observed in QuickDASH scores at 1, 3, and 6 months after treatment versus posttreatment ($P=.006$, $P=.005$, and $P=.005$, respectively). The mean QuickDASH scores are shown in figure 3, and the mean

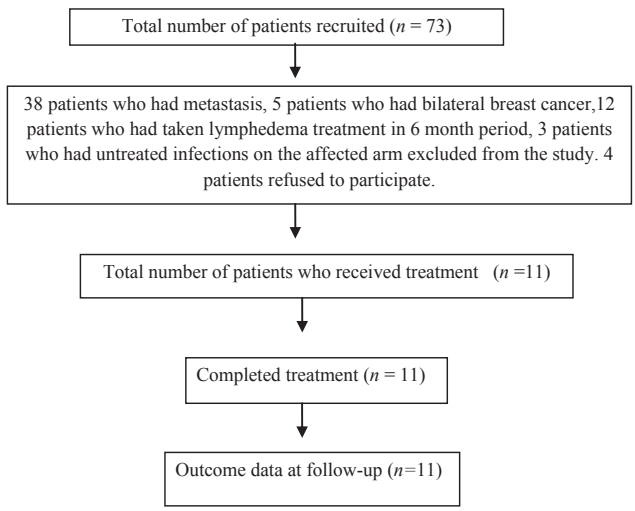

Fig 1 Flowchart of patients.

Table 1 General characteristics of the subjects (N = 11)

Characteristics	Value
Age (y)	50.63±7.03
Female	11
Lymphedema duration (mo)	12 (6–84)
Received chemotherapy	11
Received radiotherapy	8
Lymphedema severity at baseline	
Mild	1
Moderate	2
Severe	8
Lymphedema severity at 6mo after treatment	
Mild	3
Moderate	5
Severe	3

NOTE. Values are mean ± SD, median (minimum–maximum), or n.

differences of the QuickDASH scores for the follow-up period are shown in table 2.

A statistically significant improvement was seen in the scores for the physical health domain of the WHOQOL-BREF questionnaire at posttreatment and 1, 3, and 6 months after treatment in comparison with baseline scores ($P = .01$, $P = .01$, $P = .01$, and $P = .03$, respectively). In contrast, there was no statistically significant improvement observed in the physical health domain of the WHOQOL-BREF scores at 1, 3, and 6 months after treatment versus posttreatment ($P > .99$). The mean physical health domain of the WHOQOL-BREF scores are shown in figure 4, and the mean differences of the physical health domain of the WHOQOL-BREF scores for the follow-up period are shown in table 2. No changes were observed in the parameters of the psychological health, social relations, and environment domains of the WHOQOL-BREF questionnaire.

Discussion

This study was a pilot study that evaluated the effectiveness of ESWT in the treatment of breast cancer–related lymphedema. All of the patients showed significant reduction in lymphedema volume. Improvements were also observed in the QuickDASH functional assessment tool and in the physical health domain of the WHOQOL-BREF questionnaire. Treatment efficacy was maintained for all study parameters over 6 months.

Only 1 study is available in the literature on the effectiveness of ESWT in the treatment of breast cancer–related lymphedema, and the study did not focus on the long-term effectiveness of ESWT or QOL. In the study, Bae and Kim[16] explored the efficacy of ESWT treatment in 7 patients with breast cancer–related lymphedema. Four of these patients were treated with manual lymphatic drainage and pneumatic compression therapy simultaneously. Three patients were treated with ESWT only. A statistically significant reduction was observed in volumetric and circumferential measurements and visual analog scale scores in these patients after treatment. In our study, we found a similar reduction in volumetric measurements with ESWT treatment in all patients, and this reduction was maintained for 6 months. We chose not to administer any treatment other than ESWT in an attempt to focus only on the effectiveness of ESWT. Because lymphedema occurs as a result of an imbalance between the demand for lymphatic flow and the capacity of the lymphatic circulation, reconstructing the lymphatic circulation system is one promising strategy for lymphedema.[1] ESWT induces therapeutic angiogenesis by upregulating VEGF. The protein VEGF-C plays an important and essential role in lymphangiogenesis. Animal studies are available that show ESWT induces lymphangiogenesis by stimulating increased release of VEGF, thereby reducing lymphedema.[1,15] Although the exact mechanism of shock wave therapy remains unknown, the results of human studies and animal experiments have shown that ESWT promotes angiogenesis, decreases neutrophils and inflammation, and decreases the number of adipocytes.[1,15-18] Therefore, the significant reduction of lymphedema volume and long-term effectiveness of ESWT in our study could be the result of lymphangiogenesis, improvement of lymphatic drainage, and reduction of inflammation.

We also evaluated QOL and functional status of our patients. Evaluating QOL is becoming an increasingly important issue in breast cancer patients with lymphedema; however, the emotional, social, psychological, and sexual effects of breast cancer treatment have been the focus of only a few studies.[23] We found a significant improvement in QuickDASH scores, which was maintained for 6 months. QuickDASH uses a series of questions to measure the physical function and symptoms of people with any musculoskeletal disorders of the upper limbs. In our patients, pain and

Table 2 Mean difference of volumetric measurements, QuickDASH scores, and physical health domain WHOQOL-BREF scores

Time Period	Mean Difference of Volumetric Measurements (mL)	Effect Size, *d*	Mean Difference of QuickDASH Scores	Mean Difference of WHOQOL-BREF Scores	*P*
Baseline and posttreatment	134.09	.34	8.47	−.81	<.05
Baseline and first month after treatment	184.09	.46	15.08	−.81	<.05
Baseline and third month after treatment	243.18	.63	15.08	−.81	<.05
Baseline and sixth month after treatment	265.90	.69	15.08	−.72	<.05
Postreatment and first month after treatment	50.00	.12	6.61	.00*	<.05
Postreatment and third month after treatment	109.09	.28	6.61	.00*	<.05
Postreatment and sixth month after treatment	131.81	.34	6.61	.09*	<.05
Between first and third months	59.09	.14	0.30*	.00*	<.05
Between first and sixth months	81.81	.20	0.30*	.09*	<.05
Between third and sixth months	22.72	.05	0.00*	.09*	<.05

NOTE. Effect sizes (Cohen *d* score) of <0.2 are small, 0.5 are moderate, and >0.8 are large.
* $P > .05$.

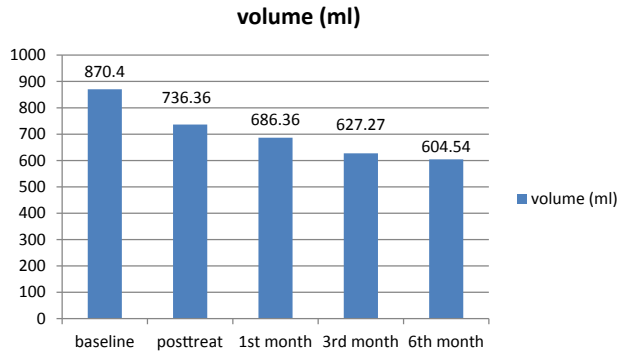

Fig 2 Mean volume displacement of the affected upper extremity at baseline, posttreatment, and 1, 3, and 6 months after treatment.

tingling in the arm, shoulder, and hand were improved as was sleep. We found another statistically significant improvement in the physical domain of the WHOQOL-BREF questionnaire, which was also maintained for 6 months. The WHOQOL-BREF questionnaire is a self-reporting questionnaire that patients can use to rate difficulty and interference with daily life. The physical health domain includes activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest, and work capacity. In our patients, especially activities of daily living and pain and discomfort parameters were improved. There was no significant improvement in the psychological, social relations, and environment domains of the WHOQOL-BREF questionnaire.

The major goal of lymphedema treatment is to reduce edema volume in the long term and therefore improve patients' QOL.[6] To our knowledge, there are no studies available in the literature that specifically evaluate the long-term efficacy of ESWT treatment alone for the management of breast cancer–related lymphedema. We found that ESWT treatment reduced lymphedema and improved QOL and functional status of patients, and its effects were maintained for 6 months.

Study limitations

A major limitation of our pilot study is the small sample size. Other limitations include absence of a placebo nontreatment group and a noncomparative design, which precluded any comparisons with other treatment methods. We planned this study to focus only on the long-term effectiveness of ESWT for breast cancer–related lymphedema; therefore, other treatment modalities were not evaluated.

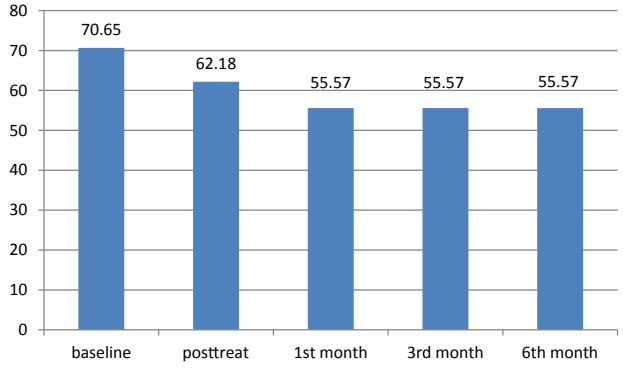

Fig 3 QuickDASH scores at baseline, posttreatment, and 1, 3, and 6 months after treatment.

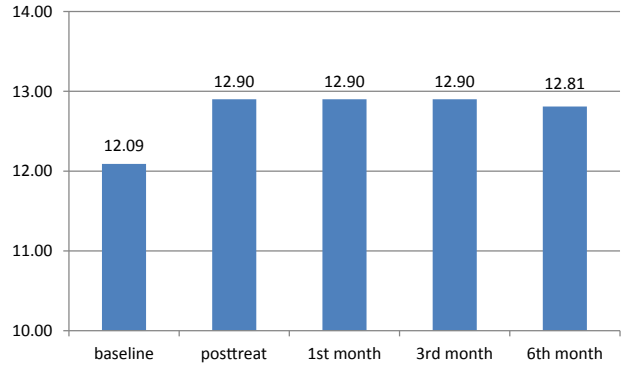

Fig 4 Physical health domain of WHOQOL-BREF scores at baseline, posttreatment, and 1, 3, and 6 months after treatment.

Conclusions

In this study, ESWT was shown to provide a reduction in the amount of lymphedema in patients with lymphedema secondary to breast cancer. Further, a marked improvement was observed in the functional impairment and QOL of study patients. Treatment efficacy was maintained over the long term. As a noninvasive, novel, and effective method, ESWT is a promising treatment modality for the treatment of lymphedema, which is a chronic, progressive, and refractory condition. Further studies with larger numbers of patients and comparative studies with other treatment modalities are needed to establish ESWT's relative effectiveness.

Suppliers

a. Vibrolith Ortho; ELMED.
b. SPSS for Windows 21; SPSS.

Keywords

Lymphedema; Rehabilitation

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