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Comparison of Extracorporeal Shock Wave Therapy and Complex Regional Decongestive Treatment in the Treatment of Postmastectomy Lymphedema: A Randomized Controlled Trial

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ABSTRACT

Objective: Lymphedema is a chronic and progressive condition that often develops after breast cancer treatments such as surgery and radiotherapy, and it is commonly managed with physical therapy-based interventions. We aimed to investigate the effect of combining extracorporeal shock wave therapy (ESWT) with complex decongestive therapy (CDT) in the treatment of breast cancer-related lymphedema.

Material and Methods: Thirty patients who developed lymphedema after mastectomy were enrolled in our study. Patients were randomly assigned to two groups (CDT or CDT+ESWT) using the closed-envelope method. Fifteen patients received CDT; fifteen patients received CDT combined with ESWT. Both groups underwent standard decongestive treatment protocols, while the CDT+ESWT group additionally received five sessions of ESWT over three weeks. Patients were evaluated at baseline, the third week, and the sixth month using the visual analog scale (VAS), quick disabilities of the arm, shoulder and hand, and limb volume and circumference measurements.

Results: There were no significant differences in baseline limb volume or demographic characteristics between the groups. At the sixth month, the mean wrist circumference was significantly lower in the CDT+ESWT group (p=0.006). In this group, the initial mean VAS score of 4.9 decreased to 2.1 after treatment (p=0.01).

Conclusion: Both treatment groups showed significant clinical improvement; however, although CDT+ESWT led to a greater reduction in pain, it was not found to be superior to CDT alone in terms of overall therapeutic efficacy.

Keywords: Lymphedema; extracorporeal shock wave therapy; complex decongestive therapy

INTRODUCTION

Lymphedema is a disorder marked by the excessive buildup of fluid rich in plasma proteins, extravascular blood components, and immunoglobulins, predominantly affecting the subcutaneous area and subfascial layer.[1] Heart failure, immobility, hypoproteinemia, pregnancy, malignancies with lymph node involvement, lymph node dissection, and radiotherapy are among the causes of lymphedema. Breast cancer is the most common malignancy among women, with lymphedema being one of its frequent complications that can occur following a mastectomy.[1,2] Lymphedema is a chronic disease that worsens over time. As a result, early detection of lymphedema and its treatment are critical to avoid complications such as infectious diseases, depressive disorder, pain, functional impairment, and malignant transformation.[2,3] According to the International Society of Lymphology (ISL), stage 2 lymphedema is characterized by persistent swelling that does not resolve with limb elevation and may show fibrotic tissue changes.

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Lymphedema, secondary to breast cancer, was first identified by Halstead in 1921 and referred to as "postmastectomy lymphedema".[4] Secondary lymphedema treatment is multidisciplinary. The incidence of lymphedema following breast cancer treatment has been reported to range from 20% to 40%, depending on surgical and radiotherapeutic factors. Common risk factors include axillary lymph node dissection, radiotherapy, infection, obesity, and delayed wound healing. Clinically, lymphedema can lead to chronic pain, recurrent infections, limb dysfunction, and psychological distress, all of which significantly impair quality of life. Complex decongestive therapy (CDT) is recognized as the gold standard treatment approach for lymphedema management. It is divided into two stages. Manual lymphatic drainage (MLD), multilayer bandaging, therapeutic exercise, and skin barrier protection were all part of phase one, which lasted 2-6 weeks. MLD is a specialized light massage technique that stimulates lymph flow through superficial vessels. Compression therapy includes multilayer bandaging and pressure garments to prevent fluid reaccumulation. Skin barrier protection involves cleansing and moisturizing to reduce the risk of infections. Remedial exercises aim to improve lymphatic circulation through muscle pump activation. When the measurements reach the plateau phase, the protection phase begins. Phase 2 of lymphedema management includes self-massage, therapeutic exercises, skincare, multilayer bandaging, and the use of compression garments. While new research is still ongoing for the treatment of lymphedema, there are methods such as laser therapy, oral drugs, pneumatic compression devices, and surgical interventions.[5,6]

Extracorporeal shock wave therapy (ESWT) is a treatment technique that applies high-intensity pressure waves to targeted areas of the body. It has been previously utilized for treating kidney stones as well as various musculoskeletal conditions like plantar fasciitis, Achilles tendinitis, epicondylitis, and osteoarthritis.[7,8] Shock waves consist of high-amplitude and short wavelength single pulsatile acoustic waves and dissipate their mechanical energy in two tissue spaces with different acoustic impedances. Shock waves can propagate in environments with acoustic properties similar to those of water without causing damage.[8] Therefore, we wondered if it would be effective in the treatment of lymphedema. ESWT promotes the early release of growth factors associated with angiogenesis, such as endothelial nitric oxide synthase and vascular endothelial growth factor (VEGF), enhancing blood circulation through induced neovascularization, consequently increasing cell proliferation and tissue regeneration.[8,9] It was also thought that it would be effective in the treatment of lymphedema due to neovascularization and lymphatic duct synthesis. Recent clinical studies have demonstrated that ESWT significantly improves limb circumference, pain, and functional outcomes in patients with breast cancer-related lymphedema, especially when combined with conventional therapies.[9,10] These findings suggest that ESWT may serve as a beneficial adjunct to standard lymphedema treatment. Based on these data, we hypothesized that the addition of ESWT to CDT would lead to greater improvements in pain, limb volume, and function than CDT alone. Therefore, the aim of this study was to investigate the effectiveness of combining ESWT with CDT in the treatment of postmastectomy lymphedema.

MATERIAL AND METHODS

Patient Selection

In this randomized controlled study, 30 breast cancer patients who developed lymphedema in the arm following mastectomy and who applied to the Physical Medicine and Rehabilitation outpatient clinic were included (Figure 1). All included patients were clinically diagnosed with stage 2 lymphedema, based on the ISL staging criteria. Participants were recruited consecutively between October 2019 and September 2020, and eligibility was assessed by two independent clinicians. Ethical approval was obtained from the Atatürk University Faculty of Medicine Ethics Committee (approval number: 01, date: September 26, 2019). The study was carried out in accordance with the principles of the Declaration of Helsinki.

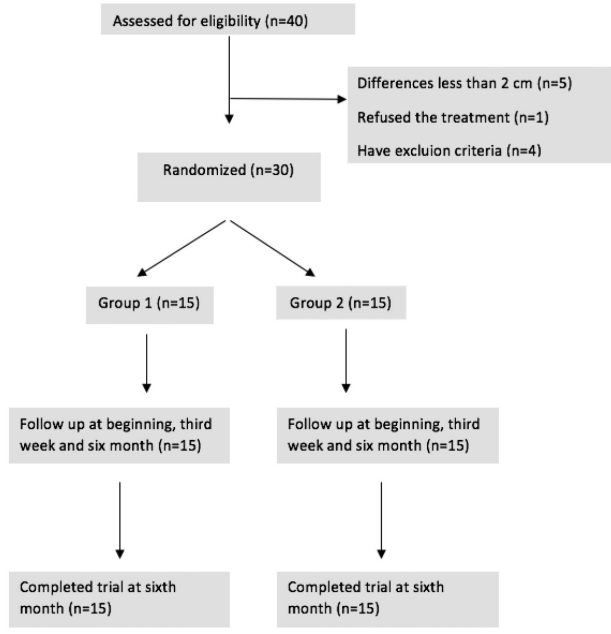

FIGURE 1: Flow diagram of the study showing the enrollment of 30 breast cancer patients with post-mastectomy lymphedema who presented to the physical medicine and rehabilitation outpatient clinic and were included in the randomized controlled trial.

The sample size was determined based on feasibility and comparability with previous studies using similar protocols (e.g., references[9,10]). A total of 30 patients (15 per group) were deemed sufficient to detect clinically meaningful differences in limb volume and visual analog scale (VAS) scores, consistent with earlier pilot studies in lymphedema research. Additionally, the limited sample size was partly due to difficulties in patient recruitment during the pandemic period.

The inclusion criteria in our study were lymphedema developed after mastectomy due to breast cancer; unilateral lymphedema; a volume difference of more than 10% between the affected and unaffected arms, which is widely accepted as a diagnostic criterion for postmastectomy lymphedema; or a difference of 2 cm in at least one region in circumferential measurement.

The exclusion criteria in our study were presence of bilateral lymphedema, active cancer or infection, venous obstruction, thrombophlebitis, pulmonary edema, history of pulmonary embolism, congestive heart failure, use of anticoagulants, and having received lymphedema treatment within the last year.

After baseline assessment, patients were randomly assigned to two equal groups (n=15 each) using a sealed opaque envelope method with computer-generated random numbers. Randomization was performed by an independent researcher not involved in patient evaluation or treatment.

Application

Thirty patients with stage 2 lymphedema were randomly assigned to two groups of 15 participants each. Randomization was performed using the closed envelope method, with a number placed inside each envelope. The first group received a complex decongestive treatment program that included MLD, compression therapy, skin care, and remedial exercise. Following MLD, which lasted approximately 30-45 minutes, intermittent pneumatic compression therapy was applied at a pressure of 40 mmHg for 45 minutes. Treatment was administered using a humidifier with a neutral pH solution. An appropriate stockinette was put on the patient's arm. The fingers and hand were then wrapped using a special technique. Compression bandaging was completed using 6, 8, and 10 cm bandages, with pressure gradually decreasing from distal to proximal. At the end of each treatment session, both upper and lower extremity exercises were performed under supervision. Lower extremity exercises were included to support overall lymphatic flow and to activate the muscle pump mechanism systemically.

In the second group, the same treatment modalities used in the first group were applied. In addition, five sessions of ESWT were administered: two sessions per week for the first two weeks, and one session in the final week. During ESWT, patients were positioned supine. Each session consisted of 2,500 shocks delivered at a frequency of 4 Hz and a pressure of 2 bar. The shocks were distributed as follows: 750 to the axillary area, 250 to the cubital area, and the remaining 1,500 to the entire upper extremity. The ESWT procedure was performed using a BTL device (Model: BTL, Serial Number: 04400B005199). The volumetric tank was locally manufactured by a skilled chrome specialist.

Assessment

In our study, patients were evaluated before the treatment, at the end (week 3), and six months after the treatment. The parameters used in the clinical evaluation were the VAS, quick disabilities of the arm, shoulder and hand (QuickDASH) score, circumference and volumetric measurements. VAS was used to assess pain intensity, and patients were asked to rate their pain from 0 (no pain) to 10 (worst imaginable pain). It is a widely validated tool in clinical research.[11] The patient's functional status was assessed using the shortened QuickDASH questionnaire. QuickDASH is a shortened version of the disabilities of the arm, shoulder and hand questionnaire. It is a self-reported outcome measure used to assess physical function and symptoms in upper limb disorders.[12] A measuring tape was used the circumference of the patient's upper extremities. The difference between the affected and unaffected upper extremities was measured. Measurements were taken at the metacarpophalangeal (MCP) joint, wrist, elbow, and 10 cm above and below the elbow. A 20-liter chrome tank was used for volumetric measurement. First, the unaffected arm and then the lymphedematous arm were immersed in the tank. The liquid overflowing from each arm separately was measured with a laboratory cup. The volume difference between the two arms was calculated as Δ where Δ = affected arm volume-unaffected arm volume. Each measurement was conducted under the same temperature and ambient conditions to minimize variability.

Statistical Analysis

Normalization of the distribution of numerical data was assessed by Shapiro-Wilk and Kolmogorov-Smirnov tests. Descriptive statistics, including mean, median, and standard deviation values, for continuous variables were calculated. The analysis of discrete distribution between the groups was conducted using either chi-square or Fisher's exact test. For continuous variables, the differences between two independent groups were analyzed using the Independent Samples t-test for normally distributed data and the Mann-Whitney U test for data that did not follow a normal distribution. Continuous variables: in the analysis of the

differences between two dependent groups, the Paired t-test was applied for normally distributed data, and the Wilcoxon test was applied for data that did not follow a normal distribution. Analysis of variance was used to compare normally distributed data across more than two independent groups, while the Kruskal-Wallis test was applied for non-normally distributed data. In the group comparison of repeated measures, the repeated measures analysis of variance was used for normally distributed data and the Friedman test for non-normally distributed data. Post-hoc tests (and Wilcoxon tests where appropriate) were used to determine the differences between groups. The confidence interval for the results was set at 95%, and the significance at $p<0.05$.

RESULTS

In the demographic data of the patients in the study, there was no significant difference between the groups regarding age, body mass index, surgery type, lymphedema duration, number of lymph nodes removed, chemotherapy, and radiotherapy history ($p>0.05$) (Table 1). Patients who had received lymphedema treatment within the past year were excluded from the study.

At the beginning in the CDT group, the mean value of the volume difference between the two extremities was 873.3, which decreased to 560 with treatment ($p<0.001$). An increase in volume of up to 750 mL was detected at 6 months ($p=0.003$). In the CDT+ESWT group, the mean volume difference was 930 mL at the beginning, and it regressed to 503.3 mL with treatment ($p<0.001$). Although there was a slight increase at 6 months, the decrease in edema was maintained compared to the baseline ($p=0.001$). When the two groups were compared, no difference was found in the mean values at day 0, week 3, and 6 month ($p=0.670$, $p=0.620$, $p=0.079$, respectively) (Table 2).

When we compared the circumference measurements, we found that the mean wrist level value at 6 months was found to be statistically significantly lower in the CDT+ESWT group patients ($p=0.006$). There was no statistically significant difference between the mean values of other upper extremity measurements, VAS, QuickDASH, upper extremity volume, and the volume differences between the two upper extremities at day 0, week 3, and month 6 ($p>0.05$). The mean values of the differences in the two upper extremities (lymphedema-normal) of the patients in the CDT and CDT+ESWT groups were compared between the groups at three time points: before treatment (day 0), after treatment (3 weeks), and 6 months after treatment. In the CDT group, the mean value of the difference in ΔMCP level in the 3rd week was statistically significantly lower ($p=0.045$) (Table 3).

When VAS values were compared, the mean value on day 0, in group 1 was 3.9 and decreased to 2.5 with treatment ($p=0.08$). The mean value increased to 3.4 at the 6th-month follow-up ($p>0.05$). The measurement on day 0 was 4.9 in the CDT+ESWT group, and it regressed to 2.1 with treatment ($p=0.01$). The mean value decreased to 1.9 at the six-month follow-up ($p=0.001$). All patients reported baseline pain symptoms and had measurable VAS scores at the beginning of the study.

When the QuickDASH data were compared, the mean value on day 0 in the CDT group was 32.1, and regressed to 24.8 with treatment ($p=0.03$). The mean value increased to 28.3 at the 6th month follow-up ($p>0.05$). The mean value on day 0 in the CDT+ESWT group was 39.2, which decreased to 27.5 with treatment ($p=0.002$). The mean value decreased to 24.3 in the 6th month of control ($p=0.001$) (Table 4).

DISCUSSION

Lymphedema is a result of the buildup of fluid, (rich in plasma proteins, extravascular blood components, immunoglobulins, cytokines) in the subcutaneous tissue and may lead to distension, adipose tissue proliferation, and progressive fibrosis development.[13] The development of lymphedema is more common in patients receiving lymph node dissection and radiotherapy due to breast cancer.[14-16] Although lymphedema is not life-threatening, it can cause disability, infections, and pain. Pain creates a feeling of discomfort over time, and this may lead to psychological issues such

TABLE 1: Demographic characteristics of group 1 and group 2.

	Group 1 (CDT) (mean ± SD)	Group 2 (ESWT+CDT) (mean ± SD)	p
Age (years)	58.8±8.2	57.7±10	0.752
Height (cm)	159.5±6.3	161.1±7.1	0.595
Weight (kg)	81.1±8.7	82.7±15.1	1.000
BMI (kg/m^2)	32±4.4	31.9±5.6	0.775
Number of lymph node dissections	19.3±5.5	21.5±8.3	0.521
Duration of lymphedema (years)	4.1±2.7	5±3	0.377

BMI: Body mass index; ESWT: Extracorporeal shock wave therapy; SD: Standard deviation; CDT: Complex decongestive therapy.

TABLE 2: Comparison of group 1 and group 2 volume difference.				
		Group 1 (mean ± SD)	Group 2 (mean ± SD)	p
Limb volume (mL)	Baseline	3343.3±478	3210±916.9	0.623
	3rd week	3030±516.1	2770±810.8	0.304
	6th month	3220±509.1	2790±892.6	0.116
ΔVolume difference (mL)	Baseline	873.3±358.5	930±361.9	0.670
	3rd week	560±351.1	503.3±260.8	0.620
	6th month	750±342.3	523.3±337.6	0.079
Δ: Volume of extremity with lymphedema-the volume of the intact extremity; SD: Standard deviation.				

TABLE 3: Comparison of groups according to the circumference differences.				
		Group 1 (mean ± SD)	Group 2 (mean ± SD)	p
Δ Elbow 10 cm above (cm)	Baseline	3.5±2.3	4.1±2.7	0.539
	3rd week	1.9±2.4	1.9±1.7	0.567
	6th month	3.1±2.3	1.9±1.8	0.902
Δ Elbow level (cm)	Baseline	3.4±2	3.8±2.1	0.345
	3rd week	1.9±1.9	1.5±1.2	0.838
	6th month	2.9±1.9	1.8±1.6	0.436
Δ 10 cm below the elbow (cm)	Baseline	3.8±2	4.1±2	0.174
	3rd week	1.8±1.7	2.1±1.4	0.089
	6th month	3.2±2	2.3±1.6	0.089
Δ Wrist level (cm)	Baseline	2±1.2	1.1±4.4	0.870
	3rd week	0.9±0.8	0.9±0.9	0.806
	6th month	2±1.5	1.2±0.9	0.089
Δ MCP level (cm)	Baseline	1.4±1.1	1.9±1.4	0.367
	3rd week	3.5±2.3	4.1±2.7	0.539
	6th month	1.9±2.4	1.9±1.7	0.567
Δ: Extremity with lymphedema-circumference of intact extremity; SD: Standard deviation; MCP: Metacarpophalangeal.				

TABLE 4: Assessment of groups according to VAS and QuickDASH.					
		Baseline	3rd week	6th month	p
Group 1	VAS	3.9±2.7	2.5±1.7	3.4±2.4	**<0.05**[a]
	QuickDASH	32.±24.5	24.8±20.3	28.3±20.6	**<0.05**[a]
Group 2	VAS	4.9±3.3	2.1±1.9	1.9±1.8	**<0.05**[a,b]
	QuickDASH	39.2±28.1	27.5±20.9	24.3±18.5	**<0.05**[a,b]
VAS: Visual analog scale; QuickDASH: Shoulder and hand score, [a]: Between baseline and 3rd week; [b]: Between baseline and 6th week					

as anxiety and depression.[17] There are physical therapy and rehabilitation programs at every stage of lymphedema treatment. Physical therapy and rehabilitation aim to prevent the occurrence of lymphedema, reduce pain after it occurs, and prevent its progression. Another aim of the therapies is to prevent the development of lymphedema after treatment.[18] In our study, both treatment groups showed significant improvements in limb volume, circumference, pain (VAS), and functionality (QuickDASH) after treatment. Moreover, the CDT+ESWT group demonstrated superior results in wrist circumference and sustained pain reduction at six months, indicating potential long-term benefits of adjunctive ESWT.

ESWT has been reported as an alternative therapeutic option for lymphedema management. Previous research suggests that ESWT increases lymphangiogenesis and alleviates secondary lymphedema by stimulating VEGF and

fibroblasts.[19,20] The increase in lymphatic drainage as a result of lymphangiogenesis may be responsible for the improvement of lymphedema in our study.

In a pilot study by Cebicci et al.[9], 2 bar 4 Hz 2500 shocks (750 axillary, 250 cubital, 1500 arm, forearm, and hand) ESWT was applied to 11 patients with breast cancer-associated lymphedema. A significant reduction in the severity of lymphedema was observed in all patients, with this improvement maintained for a period of 6 months. Improvement in QuickDASH scores was observed. These improvements continued for 6 months. However, in this study, there was no control group used for comparison, and other treatment protocols were not applied to the patient group.

In the study of Lee et al.[10], 30 patients with stage 2 lymphedema were divided into two groups. In a design similar to our study, classical CDT was given to one group, and CDT and ESWT treatment was given to the other group. VAS, circumferential measurement, volume measurement, QuickDASH, bioimpedance, and skin thickness were evaluated before and after the treatment. According to the results obtained, improvements were observed in both groups. Our study's advantage over Lee et al.[10] is the longer follow-up period (6 months in our study).

In our study, significant improvements were observed in both groups after the treatment, and at the 6th-month controls. In addition, in the group to which ESWT was added, the mean value of wrist circumference was significantly lower than that in group 1 at the 6th month. A statistically significant improvement was observed in the ΔMCP values determined for group 1 compared to group 2 in the 3rd week. There was no significant difference between the other measurements. There was an improvement in VAS and QuickDASH values in both groups. Although the CDT group showed a partial reversal at 6 months, the CDT+ESWT group maintained its improvements. In animal investigations, shockwaves caused a temporary loss of epidermal nerve fibers, which was thought to be a plausible explanation for the rapid effects of ESWT.[21] Therefore, we concluded that adding ESWT in the long term is more appropriate in terms of physical function and pain. However, it should be noted that no statistically significant difference was observed between the groups regarding volume reduction at any time point. This suggests that while ESWT may improve symptoms such as pain and wrist circumference, its contribution to overall limb volume reduction remains inconclusive.

It is established that CDT is effective in the treatment of lymphedema, and it is hypothesized that ESWT provides additional benefit when combined with CDT. However, there is a need for studies investigating the optimal number of ESWT sessions, shocks, and pressure settings.

Study Limitations

This study has several limitations that should be acknowledged. First, the sample size was relatively small, which may limit the statistical power and generalizability of the findings. Second, the lack of long-term follow-up beyond six months prevents conclusions about sustained treatment efficacy.

CONCLUSION

Lastly, blinding was not possible due to the nature of the interventions, which may have introduced observer or performance bias.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Atatürk University Faculty of Medicine Ethics Committee (approval number: 01, date: September 26, 2019).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Z.A., H.U., Concept: Z.A., H.U., Design: Z.A., H.U., Data Collection or Processing: Z.A., H.U., Analysis or Interpretation: Z.A., H.U., Literature Search: Z.A., H.U., Writing: Z.A., H.U.

Conflict of Interest: No conflict of interest was declared by the authors.

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