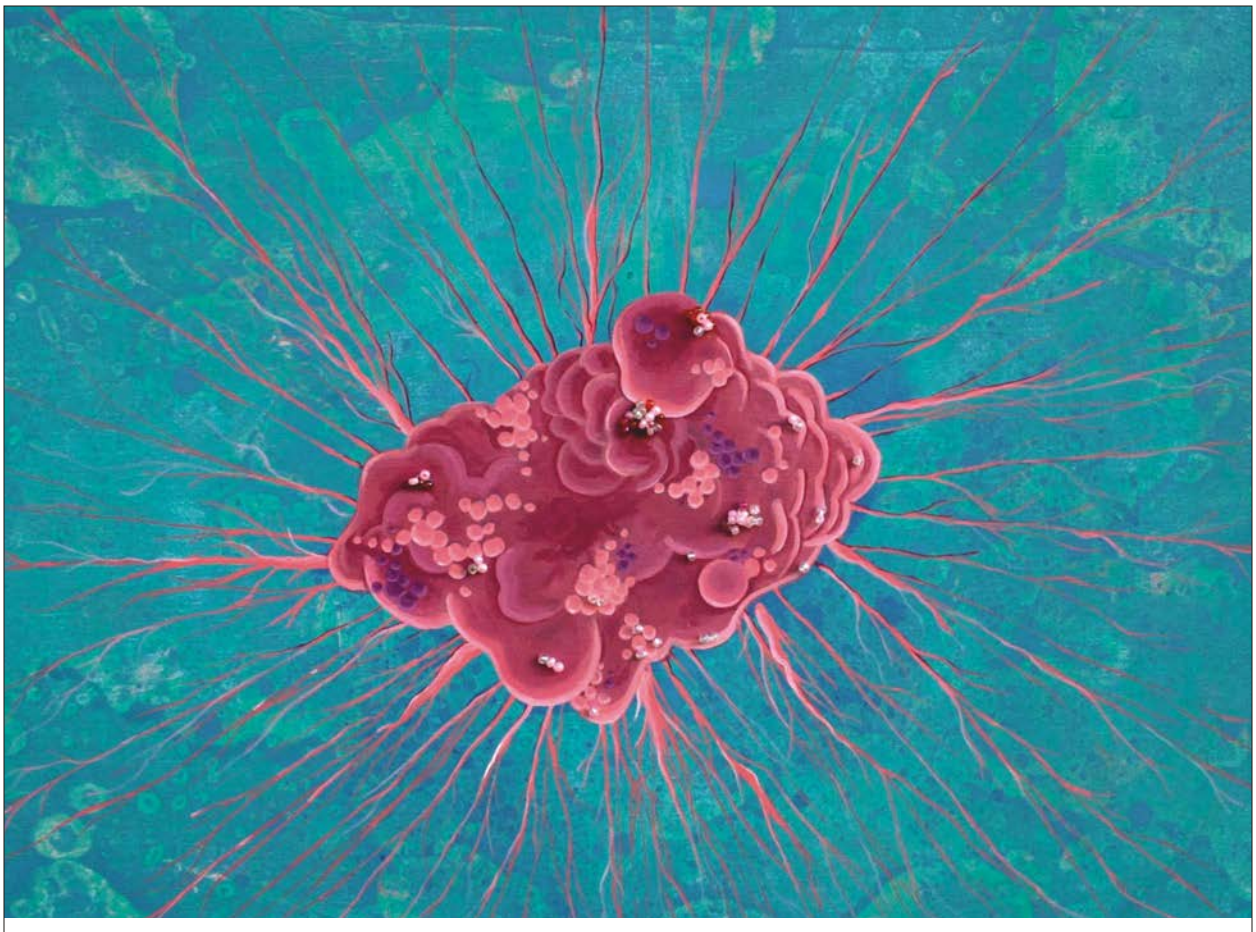

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Research Article
Comparison of Extracorporeal Shock Waves Therapy Versus Intermittent Pneumatic Compression Therapy in Breast Cancer-related Lymphedema

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Abstract

Background and Objective: The development of lymphedema in an upper extremity is one of the most common complications of breast cancer treatment. The aim of this single-blind, prospective, randomized, controlled study was to compare the effect of Extracorporeal shockwave therapy (ESWT) versus intermittent pneumatic compression therapy (IPCT) on upper limb circumferences, skin folds thickness and handgrip strength in women with lymphedema following breast cancer treatment. **Materials an Methods:** A total of 43 patients aged from 45-55 years randomly assigned to ESWT group (n = 21) who were treated by ESWT with 2500 shocks per session, 3 times/week for 4 weeks (12 sessions) with frequency of 4Hz with the energy flow density of 90 mJ and IPCT group (n = 22) who treated by IPCT with a pressure of 60 mm Hg for 45 min per session, 5 times/week for 4 weeks (20 sessions). All participants were recommended for a daily home program which included an active range of motion, pumping exercises and elevation with hygiene and skin care advice. The measures of circumferences and skin folds thickness were collected from both upper limbs at four levels by using a tape measurement and skin fold caliper, respectively. Further, the hand grip strength was measured with a hand-held dynamometer. **Results:** There were significant differences pre-treatment and post-treatment in the three outcome measures within both groups in favor of ESWT group in circumference differences and skin folds thickness while there were no significant differences between both groups in handgrip strength. **Conclusion:** It can be concluded that Extracorporeal shockwave therapy had greater improvement than intermittent pneumatic compression therapy in breast cancer-related lymphedema.

Key words: Lymphedema, extracorporeal shockwave therapy, intermittent pneumatic compression therapy

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Breast cancer is the commonest kind of cancer in women. However, the breast cancer survivors constitute about 6-38% of all patients with confirmed diagnosis[1]. Lymphedema (LE) is one of the remarkable long-term complications leading to intense functional, mental and emotional disorders in patients after treatment of breast cancer[2].

Lymphedema is a chronic cumulative problem resulting from insufficiency or destruction of the lymphatic system. Lymphedema is recognized by unusual accumulations of proteins, exudates, chronic inflammation and excessive growth of fibrous tissue. There are two types of LE, primary LE that results from congenital anomaly of lymphatic vessels[3] and secondary LE that is caused by lymphatic stasis as lymph node permeation mass, lymph node dissection, radiotherapy, injury and infection[4]. Lymphedema of upper extremity occurs in 24-49% patients with radical mastectomy and 2.4-49% patients with axillary lymph node dissection[5,6]. The presence of LE greatly interferes with the quality of life and increase the patient disability due to chronic changes in the limb size and structure either subcutaneous or integumentary[7,8].

However, the traditional treatment protocols haven't been acclaimed to be effective in the treatment of LE so far[9,10]. The complications of LE are pain, swelling, restricted range of motion, development of infection and skin sensitivity[11]. Being a chronic ongoing condition that has no cure, the treatment goals are usually directed to relieve the symptoms, to improve the psychosocial comorbidities and to restore the cosmetic semblance[12]. Different rehabilitative therapies such as elevation of the lymphatic limb, pumping exercises, manual massage, elastic wraps, intermittent pneumatic compression therapy (IPCT) and manual lymphatic drainage (MLD) are offered for the treatment of LE separately or in combination[13].

Currently, Extracorporeal shock wave therapy (ESWT) is widely used for treatment of musculoskeletal disorders. It has been acknowledged for treatment of calcified tendinitis of the shoulder, tennis elbow and calcaneal spur[14,15]. Numerous clinical trials on human and *in vivo* studies on animals have advocated using low intensity ESWT to reduce inflammation, to improve vascularization[16] and to assist lymph angiogenesis by controlling the vascular endothelial growth factor and basic fibroblast growth factor[17].

Synergistically with these biological effects, the ESWT is likely to affect the tissues by generating a direct mechanical force to the target area or indirect mechanical force through creation of cavitation bubbles that break the abnormal tissue and induce a regenerative response at the target site[18].

Intermittent pneumatic compression therapy (IPCT) is another established safe and effective method frequently used for management of LE. It has been recognized to improve the venous and lymphatic circulation by pressurizing the tissues and forcing the fluids outside the target area through a sequential inflation and deflation of a sleeve applied to the involved upper extremity[19].

Despite both the ESWT and IPCT were proved as being effective non-invasive therapies for patients with LE, applying an external forces and external compression, respectively, limited studies have argued which of them would have a more favorable effect. Therefore, the potential aim of the present study was to compare the effect of ESWT versus IPCT on upper limb circumferences, skin folds thickness and hand grip strength of lymphedema related to breast cancer treatment.

MATERIALS AND METHODS

Participants: A single-blind, prospective, randomized, controlled study was carried out at outpatient clinic of Physical Therapy Department, New Kasr El-Aini Teaching Hospital, Faculty of Medicine, Cairo University, Egypt, from January, 2017 to March, 2018. The procedures followed were in accordance with the Institutional Ethical Standards and informed consent was taken from each patient.

Forty-eight female patients were recruited based on the following inclusion criteria, aged from 45-55 years, suffering from breast cancer surgery including mastectomy and lumpectomy, they subsequently suffered from development of unilateral LE which was determined objectively by affected side to non-affected side difference of 2 cm (represented mild LE) to 8 cm (represented severe LE) at a single measurement site[20]. The patients were included if they had finished their treatments (radiotherapy or chemotherapy) within no more than 6 months. Patients were excluded upon the following, if they had bilateral LE, bilateral breast cancer, current metastasis, venous thrombosis, acute or untreated infections on the affected side and if they had joined a physical rehabilitation program within the last 6 months. Power analysis was based on estimation of the means and standard deviation of upper limb circumference at the wrist level collected from a pilot study included 10 patients who received the same intervention (5 patients treated by ESWT and another 5 patients were treated by IPCT). The mean values were 18.98 and 20.14 and standard deviations were 0.65 and 1.23, respectively. The effect size was 1.179, statistical power of 95% and an alpha of 0.05. At least a total sample of 34 subjects were required (17 for each group) and 48 subjects were recruited in this study.

Studied individuals were classified into two main groups: Participants were randomly divided into two groups by an investigator who is not involved in the study. Randomization was carried out by utilizing sealed randomly filled envelopes from a bowl including numbers of slips with either number 1 or 2 matched to the total number of participants. Number 1 was assigned to ESWT group and number 2 was assigned to IPCT group.

ESWT group: The patients in this group were treated by ESWT device (Zimmer Meizen System, enPulse version 2.0, Germany). Each patient was placed in a well-supported supine position, then received 2500 shocks/session with a frequency of 4 Hz with an energy flow density equal to a working pressure of 2 bars (90 mJ). ESWT were applied without local anesthesia to different areas of affected upper extremity 1000 shocks for lymph nodes (750 shocks for the axillary lymph nodes and 250 shocks for the cubital lymph nodes), the remaining 1500 shocks were applied to the arm, forearm and hand, 3 times/week for 4 weeks (12 sessions)[21].

IPCT group: The patients in this group were treated by an IPCT device (MJS Healthcare Ltd, UK) to apply pressure on affected arm. The Cuff pressure was 60 mm Hg without feeling any discomfort during session. All patients were comfortably seated in supported position, then a pneumatic cuff of the device was applied over the affected arm, with a pump connection to compress the air. The gradual subsequent inflation of the cuff was started from distal chambers around the hand and wrist into proximal direction, whereas chambers filled earlier were not subject to deflation (preserve suitable pressure). The session time was continued 45 min, 5 times/week for 4 weeks (20 sessions)[22].

Any side effect from ESWT or IPCT was recorded during treatment procedures. A pressure garment or a stocking wrap of affected side should be removed before the treatment intervention was begun in all patients of both groups.

All patients were recommended for a daily home program comprised active range of motion exercises, pumping exercises and elevation of affected upper extremity[23]. Hygiene and skin care advice for the patients in form of avoiding sleeping on the affected side, warding of insect bites, also preventing any suspected trauma or injury of affected upper extremity[24].

Outcome measures: The assessments were conducted by the same evaluator who was blinded to the intervention in both groups at baseline and after 4 weeks (at the end of the treatment).

- **Upper limb circumference:** A tape measurement (Lightstuff Easy Body Tape Measure, Lifestyle Product, USA) was used to measure the circumferences of the affected upper extremity at four levels, 10 cm below the axilla, 10 cm above the elbow, 7 cm below the elbow and 7 cm above the wrist[25]. Each patient was assumed a comfortable supine position, the restricting clothes were taken off. The upper extremity was relaxed beside the body with extended elbow and then the circumference measurements were measured and recorded in cm 3 times for the affected side. The final measurements were recorded by the mean values of the three measurements at each level. The non-affected side was measured at the same four levels and recorded in the same manner as the affected side. Then, the difference values between both sides were estimated for each patient as delta circumference (ΔC)[26]
- **Skin folds thickness:** A skinfold thickness caliper (Slim Guide Skinfold Caliper, Creative Health, Model C-120B, USA), was used to measure skin fold thickness at the same four levels of the circumference measurements. The patients were seated in a comfortable supported position with arms relaxed on their thigh and the restrictive clothing was removed near the area of measurements. Then the caliper was reset to zero before each set of measurement. Each measurement was taken 3 times for the affected side in millimeters. After that, the final results were determined by the mean values of 3 measurements at the same level. The skin folds thickness of non-affected side was measured on the same levels by the same method[27]. Then the difference values between both sides were calculated for each patient as delta thickness (ΔT)
- **Handgrip strength:** A calibrated hand-held dynamometer (Jamar Hydraulic Hand Dynamometer, Model Number 081028935, USA) was used to assess handgrip strength, the values were recorded in kilogram-force (kg-f). The assessment was conducted according to the protocol described by Gomes *et al*. the patients were seated in a comfortable stool, the shoulder was positioned in adduction with neutral rotation and the elbow was flexed 90°, while the forearm and wrist in a neutral position. Each patient was informed to hold the dynamometer firmly with maximum strength in response to a verbal command and after returning to neutral condition. Alternately, 3 trials were allowed for each side with an interval of not less than 1 min. The highest score represented the handgrip strength and then the recorded values were compared with non-affected side which was assessed by the same manner of the affected side of each patient[28]

Statistical analysis: All data were checked for normality using Kolmogorov-Smirnov test. The baseline differences between groups regarding the affected side, type of treatment and type of surgery were assessed using Chi-squared test. The outcome measures of upper limb circumferences, skin folds thickness and handgrip strength were analyzed between groups using independent sample t-test and within groups using dependent sample t-test. Data were considered significant if $p<0.05$. Data were analyzed by SPSS version 23.

RESULTS

The flow of the participants were showed in Fig. 1, 48 participants were randomized into 2 groups, ESWT group and IPCT group, each group had 24 patients. Three patients were withdrawn from ESWT group, 2 patients had untreated infections on the affected arm and 1 patient refused to complete the study. While 2 patients were withdrawn from IPCT group, 1 patient had metastasis of the affected arm and the other one discontinued the treatment sessions. Five patients were excluded from the study and their results were not included in the statistical analysis. The total 43 patients completed the study, 21 patients in ESWT group and 22 patients in IPCT group.

Baseline characteristics of both groups were presented in Table 1. Age and BMI were homogenous between both groups and 81% of patients in ESWT group and 82% of patients in IPCT group were dominant side ($p = 0.943$). 57% of patients in ESWT group received chemotherapy and 43% of patients treated with radiotherapy, while 50% of patients in IPCT group received chemotherapy and the other 50% treated with radiotherapy ($p = 0.643$). In ESWT group, 52.4% and 47.6% of patients were subjected to mastectomy and lumpectomy, respectively, while 63.6 and 36.4% of patients in IPCT group underwent mastectomy and lumpectomy, respectively ($p = 0.460$). No significant differences were found between both groups in both sides pre-treatment in all outcome measures (circumference measurements, skin folds thickness and handgrip strength) ($p>0.05$).

Comparisons of the differences of the circumference measurements (ΔC) between affected side and non-affected side, pre-treatment and post-treatment between both groups were showed in Table 2. The reduction in differences of circumference measurements (ΔC) at the 4 levels (below axilla, above elbow, below elbow and above wrist) revealed that there were statistically significant differences ($p<0.05$) between pre-treatment and post treatment in ESWT group versus IPCT group and there were significant differences

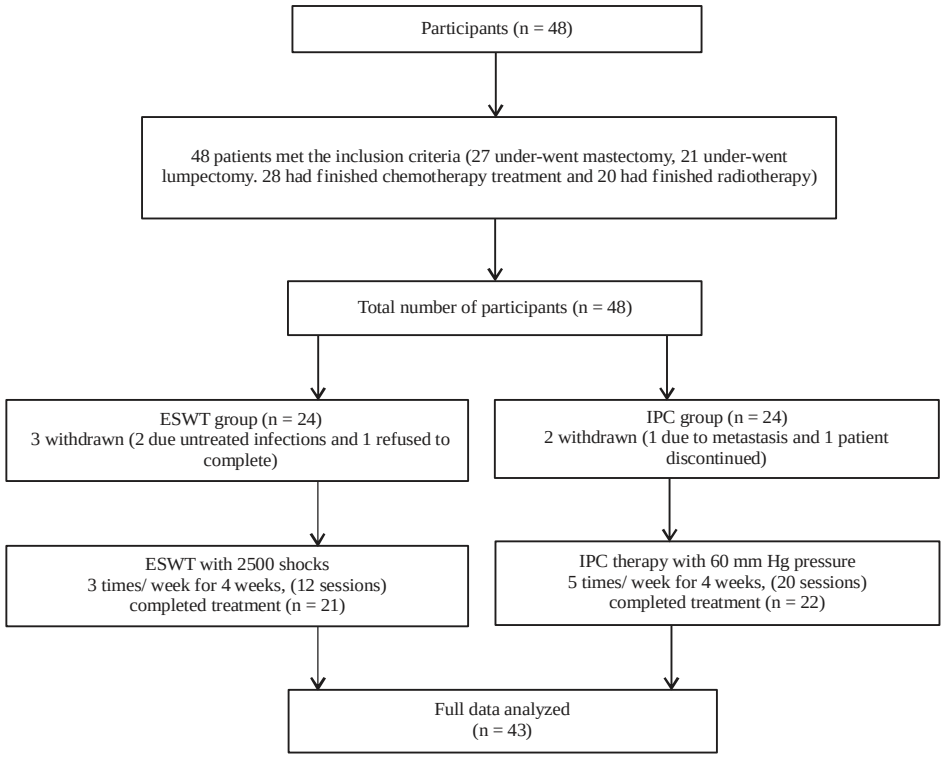

Fig. 1: Flow of participants through the study

Table 1: Baseline characteristics

Characteristics	ESWT group (n = 21)	IPCT group (n = 22)	p-value
Age	48.71±3.07	49.55±2.77	0.356
BMI	28.81±1.78	29.36±1.92	0.331
Lymphedema duration	10.95±1.59	11.17±1.61	0.709
Affected side (D/ND %)	81/19	82/18	0.943
Treatment (CT/RT %)	57/43	50/50	0.643
Surgery: (M/L %)	52.4/47.6	63.6/36.4	0.460
Circumference, non-affected side (cm)			
Below axilla	24.43±1.42	24.12±1.56	0.512
Above elbow	23.05±1.46	22.45±1.64	0.211
Below elbow	19.02±1.35	18.34±1.53	0.129
Above wrist	13.14±1.48	12.54±1.37	0.174
Circumference, affected side (cm)			
Below axilla	30.90±1.76	31.22±2.13	0.597
Above elbow	29.40±1.89	28.88±2.02	0.386
Below elbow	25.07±1.63	24.51±1.88	0.311
Above wrist	19.43±1.51	19.82±2.13	0.495
Skin folds thickness, non-affected side (mm)			
Below axilla	25.90±1.09	26.18±1.37	0.468
Above elbow	22.67±0.91	23.00±1.07	0.279
Below elbow	18.81±0.87	19.00±0.97	0.504
Above wrist	14.28±1.00	13.86±1.08	0.212
Skin folds thickness, affected side (mm)			
Below axilla	45.24±1.58	46.00±0.93	0.059
Above elbow	44.09±0.89	43.45±1.18	0.094
Below elbow	41.62±1.02	42.00±0.93	0.207
Above wrist	30.28±1.15	29.82±1.33	0.225
Handgrip strength (kg-f)			
Non-affected side	26.75±0.93	25.95±1.09	0.053
Affected side	17.86±0.79	18.19±0.96	0.234

(ESWT: Extracorporeal shockwave therapy, IPCT: Intermittent pneumatic compression therapy, D: Dominant and ND: Non-dominant, CT: Chemotherapy and RT: Radiotherapy, M: Mastectomy and L: lumpectomy, cm: centimeter, mm: Millimeter, kg-f: Kilogram-force), Data was applied in form of Mean±standard deviation with significance at p-value <0.05

Table 2: Comparisons of the differences of the circumference measurements (ΔC) between affected side and non-affected side, pre-treatment and post-treatment between both groups

	ESWT group	IPCT group	p-value
Below axilla			
Pre-treatment	6.46±0.91	7.09±3.04	0.376
Post-treatment	4.95±1.25	6.30±2.67	0.042
p-value	0.001	0.037	
Above elbow			
Pre-treatment	6.35±1.21	6.43±2.95	0.909
Post-treatment	3.45±2.19	5.28±3.02	0.029
p-value	0.001	0.001	
Below elbow			
Pre-treatment	6.04±0.92	6.17±2.55	0.827
Post-treatment	2.53±1.91	4.74±2.50	0.002
p-value	0.001	0.001	
Above wrist			
Pre-treatment	6.29±0.85	7.28±2.20	0.063
Post-treatment	2.16±1.64	5.03±2.79	0.002
p-value	0.001	0.005	

Data was applied in form of Mean±standard deviation with significance at p<0.05

(p<0.05) post-treatment between both groups in favor of ESWT group as the reduction in differences of circumference measurements (ΔC) was more than IPCT group.

Comparisons of the differences of the skin folds thickness (ΔT) between affected side and non-affected side pre-treatment and post-treatment between both groups

Table 3: Comparisons of the differences of the skin folds thickness (ΔT) between affected side and non-affected side pre-treatment and post-treatment between both groups

	ESWT group	IPCT group	p-value
Below axilla			
Pre-treatment	18.90±1.34	19.68±1.43	0.073
Post-treatment	15.71±1.62	18.05±1.89	0.008
p-value	0.001	0.001	
Above elbow			
Pre-treatment	21.43±0.81	20.95±0.98	0.096
Post-treatment	16.86±1.88	19.18±1.94	0.002
p-value	0.001	0.004	
Below elbow			
Pre-treatment	22.81±1.12	23.05±1.00	0.48
Post-treatment	16.43±3.11	18.50±2.87	0.028
p-value	0.002	0.009	
Above wrist			
Pre-treatment	15.87±1.06	16.00±1.60	0.734
Post-treatment	8.24±4.29	11.45±3.49	0.01
p-value	0.001	0.001	

Data was applied in form of Mean±standard deviation with significance at p-value <0.05

Table 4: Comparisons of the mean values of handgrip strength (kg-f) between affected side and non-affected side pre-treatment and post-treatment between both groups

	ESWT group	IPCT group	p-value
Pre-treatment			
Non-affected	26.75±0.93	25.95±1.09	0.053
Affected	17.86±0.79	18.19±0.96	0.234
p-value	0.001	0.001	
Post-treatment			
Non-affected	26.75±0.93	25.95±1.09	0.053
Affected	25.81±2.11	24.95±1.09	0.232
p-value	0.08	0.055	

Data was applied in form of Mean±standard deviation with significance at p-value <0.05

were showed in Table 3. The reduction in differences of skin folds thickness (ΔT) at the same 4 levels (as in circumference measurements) revealed that there were statistically significant differences ($p<0.05$) between pre-treatment and post treatment in ESWT group versus IPCT group and there were significant differences ($p<0.05$) post-treatment between both groups in favor of ESWT group as the reduction in differences of skin folds thickness (ΔT) was more than IPCT group.

Comparisons of the mean values of handgrip strength (kg-f) between affected side and non-affected side pre-treatment and post-treatment between both groups were showed in Table 4. There were statistically significant differences of handgrip strength (kg-f) ($p<0.05$) between affected side and non-affected side pre-treatment in both groups, on the other hand, there were non-significant differences ($p>0.05$) between both sides post-treatment in both groups and there were no significant differences between both groups post-treatment.

DISCUSSION

The current study aimed to compare the effect of ESWT versus IPCT on upper limb circumferences, skin folds thickness and handgrip strength in LE following breast cancer treatment. Nowadays, ESWT and IPCT are common physiotherapeutic modalities used in treatment of LE after breast cancer treatment. Both of ESWT and IPCT are external pressure and external compression, respectively but with different mechanical effects.

The three outcome measures, which were performed in the current study, were objective measures. Because of the anatomical variations of muscle size, muscle thickness and skin folds thickness in subject's upper extremities, the subject's non-affected arm was used as a control for the affected arm.

According to the results of this study all patients in both groups revealed a clinical improvement in the form of reduction in circumference differences and skin folds thickness, in favor of ESWT group and increasing the handgrip

strength of the affected upper extremity without detected side effects in both groups, however ESWT and IPCT were safe and non-invasive modalities in improvement of LE following breast cancer treatment.

Many clinical trials compared the effect of IPCT and others modalities in controlling LE after breast cancer treatment such as cold laser, manual lymphatic drainage, self-lymphatic drainage, elevation, pumping exercises, massage and compression bandage. To the best of knowledge, there are no clinical trials that compare between IPCT and ESWT.

In spite of the fact that the impacts of ESWT on the patients suffered from LE are unclear, it has been found to have an effect on cellular lymphangiogenesis (the growth of new lymphatic vessels) in animal. Its effect may be combined with cavitation and shear load on the hypodermis layer of the skin or its mechanical effect on tissue[17,29]. Clinical studies evaluated the effects of ESWT in patients with secondary LE found decreased circumference of LE and skin folds thickness which enhance assessment of the skin firmness. Also the progression of fibrosis was restrained after ESWT in fibrotic areas or beginning in patients with LE (stage 3)[27].

Another animal model study confirmed that, shockwave therapy decreased the enlarged skin thickness. Their results revealed that shockwave therapy improved up-regulation of VEGF-C, activation of VEGFR3 (vascular endothelial growth factor receptor 3) and increased the lymphatic duct count that promote lymphangiogenesis. It may have the mechanical stress of the low-energy ESWT, such as cavitation and shear stress[18].

Christ *et al.*[30] reported advancement of skin extensibility in the treatment of cellulitis and connective tissue defect by ESWT. They found the binding of collagen/elastic fibers in the dermis and hypodermis became compacted and hard. In biomechanical investigations, ESWT decreased oxidative stress and increased lipolysis by the liberation of poisonous aldehydic components of fat. The improvement in collagen synthesis showed visible improvement of skin condition.

On the other hand, IPCT causes increasing or descending in pressure through subsequent inflation and deflation from distal to proximal that lead to advance the redistribution of collected fluid from extracellular space into the lymphatic vessels, which reduce edema[31].

There are many protocols that have been introduced to achieve a proper implementation of IPCT. Richmand *et al.*[32] used IPC pumps in a safe manner for LE of the upper extremity at proportionately more pressure (80-110 mm Hg) for long time (6-8 h). In spite of these situations, no signs of tissue damage were discovered. Another intervention was done by Pappas and O'Donnell[33] for 4-8 h with effective long run was recorded. Yamazaki *et al.*[34] used a various protocol in which IPCT was applied day after day for 1 year. They performed a pressure of 80 mm Hg and obtained a significant reduction in LE in 57% of patients. Zanolla *et al.*[35] used IPCT in the treatment of 60 post-mastectomy patients suffering from LE of the upper limb with pressure of 90 mm Hg for 6 h for 1 week and they reported a non-significant edema reduction. Szuba *et al.*[19] carried out a study to evaluate the safety and efficacy of IPCT for the treatment of post-mastectomy LE in 2 phases. In the 1st phase they compared decongestive lymphatic therapy (DLT) with DLT in addition to daily IPCT (30 min, 40-50 mm Hg). The group received (DLT+IPC) revealed a significant decrease in volume (45.3%) compared to the DLT group (26%). In the 2nd phase, patients were treated with maintenance therapy (daily self-administered, manual lymphatic massage and class II garment) and the other group received maintenance therapy in addition to 1 h IPCT. Reduction in arm volume was observed in group that treated with maintenance therapy plus IPCT than the group that received maintenance therapy alone. The reduction was more on patients who continued to use IPCT for more 6 months.

The results of ESWT seem better than IPCT in the following, marked reduction in upper limb circumference and skin folds thickness, decreasing total number of sessions (12 sessions), each session didn't continue more than 10 min and the procedure was totally under supervision of the physical therapist. Therefore, the significant reduction in LE following breast cancer treatment in the ESWT group in the present study may be the result of lymphangiogenesis, reduction of neutrophils, inflammatory cells and adipocytes number and finally leading to renewal in skin tissue and enhancement of the lymphatic drainage.

The limitations of the current study include: (1) The subjective feeling of satisfaction about improvement were not performed because objective outcome measures were implemented, (2) No follow-up evaluation to detect the long-term effects of ESWT or IPC therapy were conducted because short-term effects were only measured and (3) Absence of placebo or sham groups because of the ethical issues, further studies will be necessary to confirm the results of the present study including subjective and quality of life investigations, follow-up evaluation to discover the long-term effects of ESWT or IPCT, to establish the cost-effectiveness of combinations of ESWT and IPCT and to identify the impact and mechanisms of ESWT in the treatment of LE following breast cancer treatment.

CONCLUSION

The outcomes of the present study suggested that extracorporeal shockwave therapy (ESWT) had a greater improvement than intermittent pneumatic compression therapy (IPCT) in reduction of upper limb circumferences and skin folds thickness of LE following breast cancer treatment, on the other hand both of ESWT and IPCT had the same positive effect on handgrip strength improvement.

SIGNIFICANCE STATEMENT

This study discovers a clinical improvement of LE following breast cancer treatment in the form of reduction in circumference differences and skin folds thickness after 4 weeks application of ESWT or IPCT, in favor of ESWT. In addition, a significant increase in handgrip strength of the affected upper extremity following application of ESWT or IPCT without detected side effects. This study will help the researcher to uncover the critical area of management of LE following breast cancer treatment that many researchers were not able to explore. Thus a new theory in improvement of LE following breast cancer treatment of high therapeutic efficacy and hopefully may be arrived at.

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