ORIGINAL PAPER

Physiotherapy Quarterly (ISSN 2544-4395)
2025, 33(2), 54–60

Radial shock wave and a tailored exercise program on axillary web syndrome after breast cancer surgery with axillary dissection: a controlled clinical trial

DOI: https://doi.org/10.5114/pq/189360

Hany Elgohary[1,2], Mohamed Elkholi[3], Rehan Abdelaziz[4]

[1] Physical Therapy Department, Faculty of Applied Medical Sciences, Jerash University, Jerash, Jordan
[2] Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Cairo, Egypt
[3] Department of Physical Therapy for Pediatrics, Faculty of Physical Therapy, Delta University for Science and Technology, Gamasa, Egypt
[4] Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Delta University for Science and Technology, Gamasa, Egypt

Abstract

Introduction. The study evaluated the effectiveness of combining radial shock wave therapy and a tailored exercise program for treating axillary web syndrome after breast cancer surgery.

Methods. Ninety-three eligible patients were randomly divided into three groups who received radial shock waves and a tailored exercise program (group A), shock wave therapy (group B), or a tailored exercise program (group C). All three groups underwent treatment over 4 weeks and were assessed for shoulder flexion and abduction, pain, thickness, echogenicity, cord disorganisation, and abbreviated disabilities of the arm, shoulder and hand (Quick DASH) assessment at the beginning and end of the interventions. The statistical analysis included descriptive statistics, tests for homogeneity, chi-squared tests, interquartile range, Kruskal–Wallis tests, and one-way analysis of variance (ANOVA) with post hoc Tukey.

Results. After the 4-week interventions, the mean differences in outcome measures indicated significant variations among the groups. Specifically, group A exhibited mean differences of –7.9 and –6.87 for shoulder flexion compared to groups B and C, respectively. For shoulder abduction, group A had mean differences of –20.17 and –10.28 compared to groups B and C, while group B exhibited a mean difference of 9.89 compared to group C. Additionally, distinct mean differences were observed for visual analogue scale (VAS), cord thickness, and Quick DASH across the groups.

Conclusions. The results suggest that combining radial shock wave therapy with a tailored exercise program provides greater benefits compared to the exercise program or radial shock wave therapy alone for patients who have undergone breast cancer surgery with axillary dissection.

Key words: lymphatic cording, breast neoplasms, dissection, exercise therapy, radial shock wave

Introduction

Axillary web syndrome (AWS) can develop after axillary dissection surgery (ADS) and is characterised by the extension of cords of subcutaneous tissue from the armpit into the arm. AWS can cause pain and restrict shoulder mobility in the affected arm. The disorder is always self-limiting and may occur early or late post-surgery [1].

AWS is often caused by injury to the axillary lymphatic system during surgery, but the exact pathophysiology is not fully understood. Some evidence from echography and magnetic resonance imaging suggests it is related to lymphatic damage [2]. AWS is usually diagnosed by physical examination, and risk factors include the extent of surgery, younger age, hypertension, lower body mass index, origin, and complications during healing [3]. The condition is considered a risk factor for lymphedema due to similar pathophysiology.

Effective clinical intervention can shorten the expected course of AWS and modify patient quality of life [4]. Treatment options include physical therapy, drug therapy, instrument-assisted soft tissue mobilisation (IASTM), thoracic manipulation and stretching, manual axial distraction, transcutaneous needle cord disturbance with fat grafting, Xiaflex injection, and surgical intervention [5]. Additionally, AWS treatment may involve active and passive stretching and cord stretching methods such as myofascial and scar release [6]. Depending on a patient's acuity and presentation, different manual approaches are used. The most helpful method is thought to be skin traction, where the therapist's thumb and index finger stretch one or 22-inch portions of the cord while the arm is abducted to a comfortable level and can be applied to the chest wall and the entire length of the cord [7]. The therapist may occasionally feel the cord pop or snap when it breaks during the stretch. In most cases, the patient experiences no pain and immediately gains more range of motion (ROM). Rather than the thickened cords observed in the axilla, this therapy frequently results in thinner piano-wire-type cords in the antecubital fossa and down the length of the cord [8].

Radial shockwave therapy (RSWT) has been used for many years to treat myofascial pain. Recent studies have shown promising results when combining low-energy extracorporeal shock wave therapy (ESWT) with complex decongestive therapy in patients with breast cancer-related lymphedema (BCRL), leading to improved ROM in the shoulder joint and skin thickness improvement. Given these positive outcomes, researchers are now exploring the potential application of RSWT in patients with AWS to enhance ROM and alleviate pain [9].

Recommending an appropriate treatment plan to lessen the negative psychological and physical impacts of AWS treatments remains a challenge, and diagnosis and treatment

Correspondence address: Hany M.I. Elgohary, Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, El-Tahrir St. Dokki, Giza, P.O. Box 11432, Egypt; e-mail: hmielgohary@gmail.com; https://orcid.org/0000-0001-5531-1875

Received: 07.01.2024
Accepted: 27.05.2024

Citation: Elgohary H, Elkholi M, Abdelaziz R. Radial shock wave and a tailored exercise program on axillary web syndrome after breast cancer surgery with axillary dissection: a controlled clinical trial. Physiother Quart. 2025;33(2):54–60; doi: https://doi.org/10.5114/pq/189360.

of the disorder require further research. Therefore, the current study investigated the combined effects of RSWT and a tailored exercise program (TEP) on AWS after breast cancer surgery with ADS.

Subjects and methods

The study was a controlled, double-blinded, randomised clinical trial (participants and assessors were successfully blinded to the group allocations) carried out at The Damietta Cancer Institute between June 2022 and December 2022. Clinical applications of RSWT, TEP, and patient physical assessments were undertaken at the outpatient clinic, Faculty of Physical Therapy, Delta University for Science and Technology. After ADS for breast cancer, a surgical oncologist diagnosed all patients with visible and/or palpable AWS and referred them to physical therapy. Patients who met the inclusion criterion of being female and between the ages of 40 and 65 were enrolled. Patients were not eligible if they had metastases of any kind, lymphedema, a traumatic injury to the targeted upper extremity, a musculoskeletal disorder, were taking any anticoagulants, had undergone bilateral breast cancer surgery, experienced locoregional recurrence, or had vascular problems in the affected upper extremity. Participants were also excluded if they declined to take part or sign the written consent form. The sample size was calculated using G*Power (Dusseldorf, Germany) to find a difference of 50% of shoulder ROM (flexion and abduction). The calculation used a confidence interval of 95% and a margin of error of 5%. Using these criteria, the estimated sample size for each group was 29 patients, and this number was increased by 15% (35 patients) to account for any dropouts between the time of randomisation and the end of the treatment protocol.

Patients were randomly assigned to receive RSWT and TEP (group A), RSWT only (group B), or TEP only (group C). The study employed block randomisation by using a computer-generated table of random numbers concealed within sealed opaque envelopes, which serves to reduce potential imbalances in participant allocation, thereby enhancing the statistical validity of the study outcomes. The concealment of the randomisation categories within sealed envelopes acts as an additional safeguard against bias, ensuring the integrity of the allocation process. The patient's shoulder ROM, pain intensity, upper extremity activities, echogenicity, thickness, and disorganisation were assessed using a digital inclinometer, visual analogue scale (VAS), an abbreviated disabilities of the arm, shoulder and hand (Quick DASH) assessment, and diagnostic ultrasound, respectively. The stratified randomisation process was overseen by a professional physical therapist who was not involved in the study procedures.

The outcomes were collected by a well-experienced investigator blinded to the group assignments and considered as part of the research team.

Assessment measures

According to Kolber et al. [10], a digital inclinometer is a reliable tool for measuring shoulder ROM. The inclinometer was placed near the shoulder at the proximal area, and with the patient's feet fixed, they moved their shoulder in different directions (flexion and abduction). The examiner repeated the measurements three times and recorded the mean value.

Pain intensity was measured using the VAS. Using a continuous 100 mm horizontal line beginning on the left side with no pain and ending on the right side with more pain, the patients marked the VAS point that corresponds to their pain level. The researcher then determined a score between 0 and 100 mm by measuring the distance (mm) on the line between the patient's mark and the "no pain" sign on the left side [11]. The measurements were taken at the start of the study as a baseline and 4 weeks after the interventions.

The Arabic version of Quick DASH is a reliable and valid measure for assessing disabilities in the upper extremities of Arabic-speaking populations, with Cronbach's alpha (0.89) indicating good internal consistency and intraclass correlation coefficient (ICC) (0.94) suggesting good test-retest reliability [12]. The measurements were taken at the start of the study as a baseline and 4 weeks after the interventions.

An ultrasonography technique involving a high-resolution ultrasound system with 18 MHz frequency provided high-definition superficial imaging that allowed measurement of cord thickness, echogenicity, and disorganisation [13]. A gel was used to reduce artefacts caused by tissue compression. The measurements were taken at the start of the study as a baseline and 4 weeks after the interventions.

Treatment procedures

Radial shock wave

The patient lay supine with the affected shoulder in an abducted position to expose the axillary cords. Each patient received 3000 shocks to different areas, including 1000 to the axillary, 500 to the upper arm, 1000 along the course of the cords, and 500 to the antecubital space. Pneumatic ESWT (EME Srl, Pesaro, Italy) was administered over two sessions during the first 2 weeks of the intervention and one session each in the third and fourth weeks. The shocks were delivered using an auto-continuous mode at 3 bar and 12 Hz, with individual shocks of 0.432 joules equating to 1296 joules per session.

Tailored exercise program

The standard exercise session consisted of a warm-up of 60 small arm swings performed for 5 min. Each stretching exercise was then executed for 2.5 min, followed by a 2.5-min rest period. The entire exercise session lasted 45 min. After completing the session, there was a two-hour rest period before repeating the exercises. Subsequently, the exercises were integrated into a home care program, with a frequency of twice a week for four consecutive weeks. The TEP involved snow angels, butterfly wings, forward pinky slides, corner stretches, chest stretches, self-tissue stretching, overhead moose stretching, and crescent side bends (Table 1).

Statistical analysis

Statistical analysis employed SPSS software for Windows, version 21.0 (IBM Corp., NY, USA). The data were used to generate descriptive statistics for the three groups at baseline and 4 weeks after treatment. Homoscedasticity was assessed using Bartlett's test before statistical analysis to determine the suitability of parametric testing. The Shapiro–Wilk test determined data distribution, while one-way analysis of variance (ANOVA) evaluated the homogeneity of groups by comparing the baseline data for age, weight, height, body mass index (BMI), arm length, cord length, VAS, active shoulder flexion, active shoulder abduction, and cord thickness. The chi-squared test analysed the distribution of data for the disorganisation and echogenicity results. One-way ANOVA with post hoc Tukey tests compared the three groups after

Table 1. Description of exercises (TEP)

Type	Description
Snow angel	Lay on your back with a rolled-up towel under the neck for support, and straighten the arms above your head with the palms facing up. Slowly slide your arms towards the head until a gentle stretch is felt, and hold this position for 30 s. Repeat the exercise five times, with three repetitions each day.
Butterfly wings	Sit on a chair with a straight back and place both hands behind the neck while pointing the elbows forward. Allow the elbows to fall out to the side until a gentle stretch is felt, and hold this position for 30 s. Repeat the exercise five times, with three repetitions each day.
Forward pinky slide	Stand facing a wall with the arm extended directly in front and rest the forearm on the wall with the pinky finger against the wall. Take a step towards the wall and allow the arm to slide up the wall until only the pinky finger touches the wall, feeling a gentle stretch. Hold this position for 30 s, take a step back, and slowly lower the arm down to the starting position. Repeat this exercise five times, with three repetitions each day.
Corner stretch	Stand in the corner with hands and forearms flat on the wall. Move the feet shoulder-width apart, with one foot taking a small step towards the wall. Slowly lean the body forward into the corner until feeling a gentle stretch across the chest. Hold this position for 30 s, then slowly return to the starting position. Repeat this exercise five times, with three repetitions each day.
Chest stretch	Stand next to a wall with the arm stretched out to the side and the palm flat against the wall. Turn the body away from the arm until feeling a gentle stretch, then hold this position for 30 s before slowly returning to the starting position. Repeat this exercise five times, with three repetitions each day.
Self-tissue stretching	Lay down on your back with the involved hand behind the head. Gently stretch the armpit towards the opposite side while lowering the elbows towards the bed. Hold this position for 30 s and then return to the starting position. Repeat this exercise five times, with three repetitions each day.
Overhead moose stretch	Stand with thumbs interlaced and resting on the head. Pull the belly button towards the spine and straighten the arms over the head. Hold this position for 30 s and then return to the starting position. Repeat this exercise five times, with three repetitions each day.
Crescent side bend	Stand up straight with a straight spine and reach the arms towards the roof, placing the palms together. Slide the scapulae down the back, lowering shoulders away from ears and pressing hips out to the right or left. Curl the upper body laterally to the left or right and hold the position for 30 s before returning to the starting position. Repeat this exercise five times, with three repetitions each day.

4 weeks of treatment for VAS, active shoulder flexion, active shoulder abduction, and cord thickness. The interquartile range analysis detected the median values for disorganisation and echogenicity at the baseline and after 4 weeks of treatment within each group. The Kruskal–Wallis test determined the *p*-values for the median disorganisation and echogenicity values within groups. A *p*-value of less than 0.05 was set as the threshold for statistical significance.

Results

AWS patients (n = 110) who underwent breast cancer surgery with ADS were recruited from the Damietta Cancer Institute. Patient eligibility was assessed by a surgical oncologist at the outpatient clinic of the Faculty of Physical Therapy, Delta University for Science and Technology. Eight patients did not meet the inclusion criteria, six declined to participate, and three were excluded for other reasons. The patients were then referred to physical therapy. Figure 1 illustrates the patient flow diagram.

The remaining 93 eligible patients were randomly assigned to one of the three groups. Three patients (one from the combined therapy group, one from the RSWT group, and one from the TEP group) could not complete the study due to transportation issues.

No adverse effects of the treatment protocol were reported in any of the groups, according to the feedback provided by the patients. The baseline data for all bio-demographic and clinical characteristics, such as age, weight, height, BMI (body mass index), arm length, shoulder flexion and abduction, VAS, cord length, thickness, echogenicity, disorganisation, length, and Quick DASH, did not show any statistically significant differences between the groups (Tables 2 and 3).

Table 2. The Baseline characteristics of patients in groups A, B, and C

Variable	Group A (mean ± SD)	Group B (mean ± SD)	Group C (mean ± SD)	*p*-value
Age (year)	56.67 ± 8.24	56.03 ± 7.19	56.53 ± 7.74	0.95
Weight (kg)	66.33 ± 6.84	66.50 ± 6.49	66.93 ± 6.12	0.93
Height (m)	1.62 ± 0.06	1.63 ± 0.06	1.60 ± 0.04	0.14
Cord length (cm)	13.78 ± 2.92	13.58 ± 2.95	13.82 ± 4.08	0.96

The *p*-values for the comparison of the variables across groups A, B, and C were obtained using one-way analysis of variance.

Table 3. Baseline characteristics of cord organisation and echogenicity for groups A, B, and C

Variable	Group A	Group B	Group C	*p*-value	Chi-square value
Cord organisation					
disorganised	12 (40%)	13 (43.33%)	9 (30%)	0.27	7.59
poor organised	12 (40%)	8 (26.67%)	12 (40%)		
organised	1 (3.33%)	6 (20%)	7 (23.33%)		
well organised	5 (16.67%)	3 (10%)	2 (6.67%)		
Cord echogenicity					
hyperechoic	7 (23.33%)	7 (23.33)	6 (20%)	0.94	1.79
moderate echoic	11 (36.67%)	8 (26.67%)	12 (40%)		
isoechoic	6 (20%)	9 (30%)	6 (20%)		
hypoechoic	6 (20%)	6 (20%)	6 (20%)		

The *p*-values for the comparison of variables across groups A, B, and C were obtained using a chi-squared test.

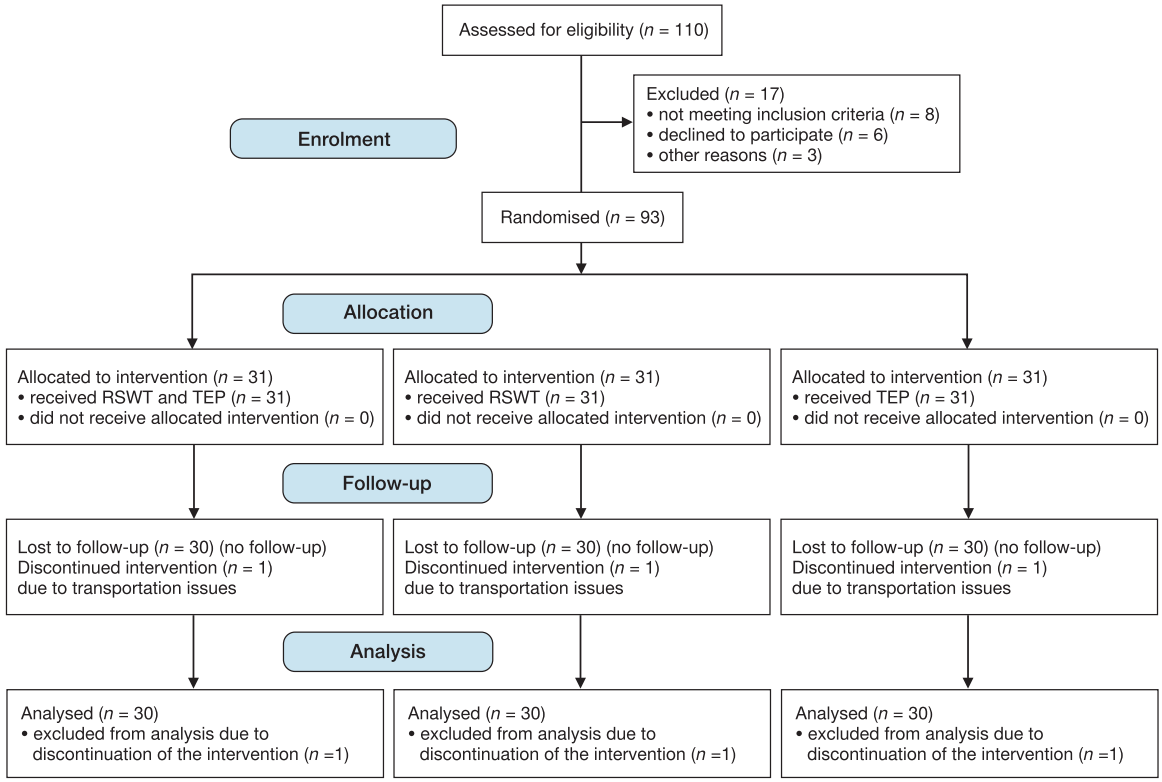

Figure 1. Flowchart of the participants during the trial

The results showed that the mean values of VAS, shoulder flexion and abduction, cord thickness, and Quick DASH were significantly different between baseline and after 4 weeks of intervention ($p < 0.05$) (Table 4).

When analysing the mean differences and 95% confidence intervals for various outcome measures (shoulder flexion and abduction, VAS, cord thickness, and Quick DASH) across the three, the findings indicated that group A exhibited higher values than group B. Additionally, group C demonstrated lower values than groups A and B. Notably, the results indicated non-significant differences between groups B and C across most of the compared variables, as evidenced by the *F*-statistics and *p*-values in Table 5.

Table 4. Comparison of variables across groups A, B, and C before and after treatment

Variable	Time	Group A (mean ± *SD*)	Time	Group B (mean ± *SD*)	Time	Group C (mean ± *SD*)	*p*-value
VAS	pre	7.00 ± 1.68	pre	7.17 ±1.77	pre	7.07 ± 1.62	0.91
	post	1.13 ± 0.57	post	2.2 ±1.56	post	1.60 ± 1.1017	< 0.001*
p-value	< 0.001*		< 0.001*		< 0.001*		
Active shoulder flexion	pre	139.08 ± 13.65	pre	139.22 ±17.30	pre	138.53 ± 17.19	0.98
	post	174.73 ± 5.27	post	166.83 ± 8.39	post	167.86 ± 3.18	< 0.001*
p-value	< 0.001*		< 0.001*		< 0.001*		
Active shoulder Abduction	pre	127.47 ± 22.08	pre	127.95 ±19.37	pre	127.91 ± 25.31	0.99
	post	176.49 ± 2.73	post	156.32 ± 21.18	post	166.21 ± 7.06	< 0.001*
p-value	< 0.001*		< 0.001*		< 0.001*		
Cord thickness	pre	0.32 ± 0.05	pre	0.33 ± 0.14	pre	0.32 ± 0.14	0.99
	post	0.03 ± 0.03	post	0.22 ± 0.09	post	0.29 ± 0.09	< 0.001*
p-value	< 0.001*		< 0.001*		0.019		
Quick DASH	pre	79.73 ± 6.63	pre	80.60 ± 6.25	pre	80.17 ± 6.78	0.88
	post	29.3 ± 8.59	post	45.87± 7.97	post	41.93 ± 9.09	< 0.001*
p-value	< 0.001*		< 0.001*		< 0.001*		

VAS – visual analogue scale, pre – baseline, post – after 4 weeks of intervention
* statistically significant
The *p*-values for the comparison of variables across groups A, B, and C were obtained using one-way analysis of variance.

Table 5. Comparison of mean differences, 95 % confidence intervals, degrees of freedom, F-statistics, and p-values for shoulder flexion and abduction, VAS, cord thickness, and Quick DASH across groups A, B, and C

Variable	Groups	MD (CI 95%)	*df*	*F*-statistic	*p*-value
Shoulder flexion	A vs. B	–7.9 (–14.65, 1.15)	[1–58]	6.37	0.01*
	A vs. C	–6.87 (–13.62, 0.12)	[1–58]	7.81	0.01*
	B vs. C	1.03 (–5.72, 7.78)	[1–58]	0.13	0.72
Shoulder abduction	A vs. B	–20.17 (–28.16, –12.18)	[1–58]	26.77	< 0.001*
	A vs. C	–10.28 (–18.28, –2.29)	[1–58]	55.42	< 0.001*
	B vs. C	9.89 (1.89, 17.88)	[1–58]	5.89	0.02*
VAS	A vs. B	1.07 (0.46, 1.67)	[1–-58]	20.51	< 0.001*
	A vs. C	0.47 (–0.14, 1.07)	[1–58]	4.24	0.04*
	B vs. C	–0.60 (–1.20, 0.01)	[1–58]	4.23	0.04*
Cord thickness	A vs. B	0.19 (–0.27, 0.66)	[1–58]	135.61	< 0.001*
	A vs. C	0.45 (–0.01, 0.92)	[1–58]	143.69	< 0.001*
	B vs. C	0.26 (–0.21, 0.72)	[1–58]	1.16	0.29
Quick DASH	A vs. B	16.57 (11.29, 21.84)	[1–58]	59.88	< 0.001*
	A vs. C	12.63 (7.36, 17.91)	[1–58]	30.57	< 0.001*
	B vs. C	–3.93 (–9.21, 1.34)	[1–58]	3.17	0.08

VAS – visual analogue scale, *F*-statistic – *F* = MS between/MS within, where MS between is the mean square between groups and MS within is the mean square within groups
Mean differences, confidence interval (95 %), degrees of freedom, *F* and *p*-values were obtained using one-way analysis of variance with post hoc Tukey tests.

Table 6. Interquartile range of disorganisation and echogenicity

Variable	Group	Time	IQR	Median (min–max)	Percentage of improvement	*p*-value
IQR for disorganisation	A	pre	1	2 (1–4)	100	< 0.001*
		post	0	4 (2–4)		
	B	pre	2	2 (1–4)	50	< 0.001*
		post	1	3 (1–4)		
	C	pre	2	2 (1–4)	50	< 0.001*
		post	0	3 (2–4)		
IQR for echogenicity	A	pre	1	2 (1–4)	100	< 0.001*
		post	0	4 (3–4)		
	B	pre	1	2.5 (1–4)	60	< 0.001*
		post	1	4 (1–4)		
	C	pre	1	2 (1–4)	100	< 0.001*
		post	0	4 (2–4)		

IQR – interquartile range, pre – baseline, post – after 4 weeks of intervention
* derived from the Kruskal–Wallis test

When measuring the interquartile range of cord disorganisation and echogenicity at baseline and after 4 weeks of intervention, the results showed statistically significant differences among the three groups, with higher percentages of improvement in group A compared to B and C (Table 6).

Discussion

The study investigated the effectiveness of RSWT, TEP, and combined therapy (LESW and TEP) in treating AWS in breast cancer patients following ADS. No negative effects were reported for any of the treatment protocols in any of the three groups.

The baseline demographic and clinical data showed no significant variation between the groups. However, after 4 weeks of intervention, the mean differences in VAS, shoulder flexion and abduction, cord thickness, and Quick DASH were significantly differences between the groups. Specifically, group A had higher values than group B and lower values than group C. In addition, the interquartile range of cord disorganisation and echogenicity varied between the three groups, with maximum improvement observed in group A, followed by group B and group C.

The findings suggest that RSWT combined with TEP may be effective for treating AWS in breast cancer patients following ADS. However, group A seemed to have higher improvement rates than the other two groups, indicating the potential for further optimisation of treatment protocols to improve overall patient outcomes.

A prospective clinical trial by Bae and Kim [14] with a small sample size of seven participants compared the effectiveness of RSWT on breast cancer-related lymphedema with and without lymphatic massage. The authors described the trial's constituent elements, including study population characteristics, ESWT setting parameters, and methods of clinical outcome measurement evaluation. Both groups showed marked improvement in the measured outcomes, including upper extremity volume, circumferences, and skin thickness, but no significant difference was found when comparing the two groups [14].

The current study has important clinical implications, as AWS can substantially impact the quality of life of breast cancer survivors. As such, RSWT and TEP could offer a safe and effective treatment option for AWS symptoms.

Based on a search for studies that are parallel to or contradict our study on the combined effect of RSWT and TEP on AWS after mastectomy with ADS, a study published in 2022 investigated the effectiveness of RSWT for breast cancer-related lymphedema. The study found that RSWT significantly reduced the affected limb's volume and improved symptoms compared to the control group. The findings of this study are in agreement with our work and demonstrate the potential effectiveness of RSWT in improving symptoms related to breast cancer surgery [15].

Consistent with the existing literature, we found that AWS can be triggered by various factors, including radiation therapy and specific types of breast cancer. Previous studies have shown that RSWT can induce positive effects such as pain relief, angiogenesis, protein synthesis, cell proliferation, nerve and cartilage protection, and disruption of calcium deposits in musculoskeletal structures [16–18]. These combined effects have the potential to promote tissue regeneration, provide significant pain relief, and enhance the functionality of damaged tissue [19–23]. Our study involved stretching exercises designed to improve ROM and reduce tension in the affected area. Physical therapy, including stretching exercises, is a widely used treatment option for AWS, and our research supports its effectiveness. In summary, our controlled clinical trial explored the potential of ESWT and TEP in managing AWS following breast cancer surgery with ADS. We observed promising outcomes in terms of pain relief, improved ROM, and functional improvement in the damaged tissue. However, further research is needed to validate these findings and establish optimal protocols for ESWT and TEP use in AWS management.

Limitations

Limitations of the current study include the lack of a placebo control group. Since all participants received some form of treatment, it is challenging to determine if the improvement was due to the treatment itself or simply the passage of time. Additionally, the short follow-up period could not detect any potential long-term benefits or adverse effects of the treatments being tested. Another limitation is the heterogeneity of the study population, as the effectiveness of treatments may vary depending on the severity of the condition. Therefore, future studies with longer follow-up periods are needed to confirm the efficacy of this intervention and its long-term effects. Recommendations for future studies include increasing the diversity of participants, as this can improve the generalisability of the findings. Additionally, using a placebo control group can accurately assess the effectiveness of the interventions, while a longer follow-up period can provide insights into any potential long-term benefits or adverse effects of the treatments. Conducting stratified or subgroup analyses based on the severity of the condition or other relevant demographic or clinical factors can also help evaluate the interventions' efficacy.

Conclusions

The findings of this study suggest that combining shock wave therapy with a tailored exercise program provides more significant advantages compared to the exercise program or shock wave therapy alone for patients who have undergone breast cancer surgery with axillary dissection.

Acknowledgements

We would like to thank our friends and family for their unwavering support, encouragement, and motivation throughout this journey. Their love and encouragement have enabled us to persevere through challenges and reach this important milestone.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Ethical Committee for Human Research at the Faculty of Physical Therapy, Delta University for Science and Technology, Egypt (approval No.: F.P.T 2207006). The study was registered at ClinicalTrials.gov (NCT05920369).

Informed consent

Informed consent has been obtained from all individuals included in this study.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

Funding

This research received no external funding.

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