Efficacy of Extracorporeal Shock Wave Therapy on Shoulder Dysfunction Post Mastectomy
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ABSTRACT
Background: Post mastectomy shoulder pain can be severe enough to result in long-term difficulties, disrupt sleep, impair the ability to carry out daily tasks, including using the affected arm, and result in frozen shoulder.
Objective: The aim of the current study is to assess the effectiveness of extracorporeal shock wave on shoulder dysfunction post mastectomy.
Patients and methods: The study was conducted on 40 patients undergoing mastectomy between the ages of 40 and 65 who experienced shoulder pain and limited range of motion and were randomly split into two equal groups, each with 20 patients. Group A (Study group): For eight weeks, extracorporeal shockwave therapy (ESWT) was administered once a week to 20 patients of females receiving traditional physical therapy three times per week. Group B (Control group): 20 female patients who got only traditional physical therapy three times a week a week with sham- shock wave once a week for eight weeks were included in this group.
Results: There was a significant increase in the measurement of passive range of motion for shoulder abduction, flexion, external rotation and internal rotation in the post-treatment assessments compared to the baseline measurement (P<0.001) and by comparing both groups, there were a statistically significant higher ROM in Group A than Group B (P< 0.001). Also, a significant increase in the measurement of active ROMs for shoulder abduction, flexion, external rotation and internal rotation in the post-treatment assessments compared to baseline measurement (P<0.001). Conclusion: Extracorporeal shock wave therapy is more effective than conventional physical therapy in the treatment of patients with shoulder dysfunction following mastectomy.
Keywords: Extracorporeal shockwave therapy, Shoulder Dysfunction, Postmastectomy, Comparative study, Cairo University.

INTRODUCTION
Modified radical mastectomy involves complete removal of the breast, the majority or all of the ipsilateral axillary lymph nodes, and the lining over the chest muscles are all completely removed during a mastectomy. In a radical mastectomy, every lymph node beneath the arm, along with the entire breast and the supporting chest wall muscles (including the pectoralis major and minor muscles), are removed (1).

There are many non-surgical treatment options for shoulder dysfunction, including thermotherapy, psychotherapy, electric percutaneous nerve therapy, ultrasound therapy, manual therapy, and taping therapy. Extracorporeal shockwave therapy (ESWT) has recently gained attention (2).

Many women who had breast cancer mastectomy endure shoulder movement limitation thereafter, which can seriously impact their daily lives and quality of life (3). Shoulder limitation and disability are about six times more prevalent in women who have undergone mastectomy (4). Despite more advanced surgical methods and after care, discomfort and functional limitations continue to be issues for individuals who have breast-conserving surgery (5).

The complex shoulder girdle movements necessary for arm raising may potentially be impacted by the aftereffects of surgery or radiotherapy. Normally, the humerus and scapula move together smoothly and in synchronicity (6).

The head of the humerus is kept in the glenoid fossa throughout the movement by precise muscle firing of the scapulothoracic and scapulohumeral muscles in response to sophisticated proprioceptive input (7).

Joint synovial membranes thicken and stick to articular surfaces as a result of shoulder adhesion, which causes discomfort to progressively worsen and joint range of motion to gradually deteriorate. Even though frozen shoulder does not itself result in neurogenic muscle weakness like cervical radiculopathy, it does cause pain, reduce external rotation of the shoulder joint, decrease flexibility and elasticity, and make daily activities challenging due to the associated joint fibrosis and chronic inflammation (8).

ESWT is a technique of treatment that involves the application of extracorporeal shock waves to lesions in order to promote revascularization and stimulate or reactivate the repair of bones and connective tissues,
AIM OF THE STUDY
The study’s goal was to ascertain the impact of extracorporeal shock wave on shoulder dysfunction post mastectomy.

PATIENTS AND METHODS
Study Design:
Two parallel groups were studied in a randomized, controlled study using a pretest-posttest design between May 2022 and March 2023.

Participants:
A total of 40 female patients had been conveniently selected as a sample from Helwan University Hospital to be treated, at the period between May 2022 and March 2023. They had been enrolled and assessed for their eligibility to take part in the study. Patients were included if they had the development of the shoulder dysfunction (range of motion [ROM] limitation and shoulder pain) post mastectomy. Patients were 3 months–6 months’ post mastectomy and (at the time of surgery) ranged in age from 40 to 65. Patients who had previously undergone shoulder surgery, a history of shoulder fracture, malignancy, inflammatory disorders, bleeding disorders, or diabetes, unwillingness to participate in the study, patients with structural problems, Patient with recent dislocations or subluxations, patient with rheumatic disease and Patient who underwent surgery were excluded from the study.

Randomization
The participants were aware of the nature, goal, and benefits of the study, as well as their freedom to decline or withdraw at any time and the confidentiality of any information they received. All data were coded, ensuring anonymity. Two groups of patients with shoulder dysfunction following mastectomy had been randomly assigned (A and B) by means of a blinded and impartial research assistant who opened sealed envelopes containing a computer-generated randomization card.

Interventions
Patients randomly allocated to the study group (Group-A): In Group-A, 20 female patients got shock wave therapy once a week with traditional physical therapy, 3 sessions/week ,program for 8weeks.
Control group (Group-B): 20 female patients got sham-shock wave therapy once a week with traditional physical therapy, 3 sessions/week ,program for 8weeks.
Traditional physical therapy program composed of: Joint mobilization, Active exercise and non-painful passive ROM exercises. The sham- shock wave had been administered in (Group-B) by identically to how the real had been in (Group-A). The sham probe is similar in design, sound and shape, but no real shock waves were applied.

Outcome Measures
The outcome measures included shoulder pain, ROM of the affected limb. All assessments were conducted by physiotherapists pre- and post-treatment.

Shoulder function Assessment
“American Shoulder and Elbow surgeons Evaluation Form” (ASES). The ASES score can be thought of as a scale that assesses two aspects of shoulder function: pain and functionality during daily activities.
A score of 0 indicates a worse shoulder condition, while a score of 100 indicates a better shoulder condition, a systematic procedure for evaluating shoulder function

Shoulder ROM assessment
Goniometric measurement
The assessment protocol was done for all patients to measure ROM for external and internal rotation, shoulder flexion, and abduction.
- flexion, abduction, internal, and external rotation at a neutral posture using a stainless-steel goniometer. Passive ROMs (pROMs) and active ROMs (aROMs).
- Each individual sat on a stool, and a goniometer was used to measure the ROM in each direction.
- While the pROMs was assessed by the examiner moving each subject's arm until it was mechanically or painfully limited, the aROMs was measured with the instruction that participants should move their arm as far as they could.

Statistical Analysis and Sample Size Calculation
With the aid of the IBM SPSS software package version 25.0, data were input into the computer and evaluated. For variables with tiny predicted numbers, Fisher’s exact test and the Chi square test were used to explain qualitative data using numbers and percentages. The normality of the distribution was examined using the Kolmogorov-Smirnov test. The range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR) of quantitative data were used to characterize them, and the independent t-test or Mann Whitney test was used to compare them.

Ethical Approval
The Faculty of Physical Therapy at Cairo University’s Ethics Committee approved the human-use research after it met with all applicable national rules, institutional policies, and the precepts of the Declaration of Helsinki (N0:P.T.REC/012/003510)
Informed Consent
Informed consent had been obtained from all individuals included in this study.

RESULTS

Patients’ demographics and characteristics

Both groups had comparable ages, with the mean age in Group A being 48.50 (SD 5.47) years and the mean age in Group B being 50.05 (SD 4.58) years without a statistically significant difference between both groups (P=0.84); additionally, no statistically significant There was no difference in the two groups’ weight, height, BMI, or months of symptom duration. (P >0.05) (Table 1).

Comparison of pre- and post-treatment points of ASES scale and shoulder passive and active ROM within Group A and Group B

Regarding pretreatment baseline data there was no statistically significant difference between both groups for ASES scale and shoulder passive and active ROM (P>0.05)

The ASES scale show statistically significant improvement in both groups post-treatment compared with pre-treatment. However, Group A showed a statistically significant higher post-treatment ASES scale (89.25 ± 4.38) compared to group B (60.25 ± 7.34) (P<0.001).

Table 2 demonstrates evidence of a considerable improvement in the measurement of passive ranges of motion (ROMs) for shoulder abduction, flexion, external rotation, and internal rotation in comparison to the baseline measurement. (P<0.001), and by comparing both groups, we found a statistically significant higher ROM in Group A than Group B (P<0.001).

Table 2 also illustrated a significant increase in the measurement of active ROMs for shoulder abduction, flexion, external rotation and internal rotation in the post-treatment assessments compared to the baseline measurement (P<0.001), and by comparing both groups, a statistically significant higher ROM was found in Group A than Group B (P<0.001).

Table 1: Basic clinical data in the study groups.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (n=20)</th>
<th>Group B (n=20)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD.</td>
<td>Mean ± SD.</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>48.50 ±5.47</td>
<td>50.05 ±4.58</td>
<td>0.841</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>89.90 ±8.68</td>
<td>90.40 ±8.67</td>
<td>0.799</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.90 ±4.38</td>
<td>165.00 ±3.97</td>
<td>0.925</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>32.95 ±3.91</td>
<td>33.05 ±3.92</td>
<td>0.904</td>
</tr>
<tr>
<td>Symptom duration months</td>
<td>4.75 ±0.97</td>
<td>4.80 ±0.77</td>
<td>0.968</td>
</tr>
</tbody>
</table>

SD: Standard deviation, P: P-value for comparing between the 2 studied groups. *: Statistically significant at P<0.05.

Table 2: Comparison of pre- and post-treatment points of ASES scale and shoulder ROM (p, a) within Group A and Group B.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A (n=20)</td>
<td>Group B (n=20)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean ± SD.</td>
<td>Mean ± SD.</td>
<td></td>
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<td></td>
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<tr>
<td>Points of ASES scale</td>
<td>56.25 ±8.09</td>
<td>54.50 ±6.67</td>
<td>0.277</td>
</tr>
<tr>
<td></td>
<td>89.25 ±4.38</td>
<td>60.25 ±7.34</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Passive ROMs (pROMs) of shoulder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abduction</td>
<td>108.25 ±8.74</td>
<td>111.75 ±11.95</td>
<td>0.149</td>
</tr>
<tr>
<td>Flexion</td>
<td>122.00 ±6.74</td>
<td>126.10 ±6.10</td>
<td>0.091</td>
</tr>
<tr>
<td>External rotation</td>
<td>59.05 ±7.22</td>
<td>56.45 ±8.61</td>
<td>0.445</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>61.50 ±5.25</td>
<td>59.85 ±6.02</td>
<td>0.529</td>
</tr>
<tr>
<td></td>
<td>143.15 ±3.82</td>
<td>120.00 ±8.74</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>170.75 ±5.60</td>
<td>136.70 ±4.18</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>84.70 ±4.87</td>
<td>66.25 ±11.38</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>84.55 ±3.33</td>
<td>66.75 ±8.19</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Active ROMs (aROMs) of shoulder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abduction</td>
<td>97.25 ±7.69</td>
<td>100.25 ±11.53</td>
<td>0.201</td>
</tr>
<tr>
<td>Flexion</td>
<td>126.45 ±9.03</td>
<td>122.85 ±6.05</td>
<td>0.108</td>
</tr>
<tr>
<td>External rotation</td>
<td>53.05 ±6.51</td>
<td>51.50 ±7.86</td>
<td>0.779</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>57.00 ±4.96</td>
<td>55.10 ±6.61</td>
<td>0.602</td>
</tr>
<tr>
<td></td>
<td>135.75 ±4.49</td>
<td>112.75 ±10.45</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>160.40 ±5.02</td>
<td>127.55 ±5.33</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>70.50 ±5.44</td>
<td>57.95 ±9.40</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>78.35 ±4.03</td>
<td>61.90 ±8.00</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

SD: Standard deviation, P: P value for comparing between the two studied groups. *: Statistically significant at P ≤ 0.05
DISCUSSION

This study was conducted to determine the efficiency of extracorporeal shock wave on shoulder dysfunction post mastectomy.

The measurement of shoulder abduction, flexion, external rotation, and internal rotation showed a substantial rise in the current study's results, along with a significant improvement in the ASES scale in group A post-treatment compared to group B. This result goes in parallel with Qiao et al. (12) whom putting together a program to study how ESWT affects the pain and functioning of people with frozen shoulder. It was predicted that ESWT would significantly improve shoulder pain and functionality in frozen shoulder compared to control groups.

Low-energy shock-wave therapy may generate analgesia, however it is unclear how. Brain-stem processes that exert a descending inhibitory regulation of transmission through the dorsal horns as well as at higher levels in the somatic projection system are thought to be responsible for controlling pain caused by severe stimulation. According to claims, the strong input activates small-diameter fibers that project to cells in the periaqueductal grey regions. The serotonergic system is then activated by these, and it eventually modifies transmission through the dorsal horns. Small-fiber inputs make up the feedforward phase of the system's intricate feedback loop, while the descending inhibitory system serves as the feedback portion (13).

According to several studies, ESWT appears to exert its anti-inflammatory effects through suppressing NF-kappaB activation and NF-kappaB-dependent gene expression (14,15).

ESWT reduced the intracellular levels of TNF-alpha and IL-10 in chondrocytes, which may have helped OA chondrocytes produce more TNF-alpha and IL-10 than usual (15). An interesting clinical study by Brañas et al. (16) ESWT decreased chondrocytes’ intracellular levels of TNF-alpha and IL-10, which may have encouraged OA chondrocytes to manufacture more of these substances than usual.

Local injured tissue cell proliferation is improved by ESWT (17-20), extracellular matrix metabolism triggered (20), decreased apoptosis (18,21), additionally promising and call for additional clinical research include down-regulated oxygen-mediated burst of leukocytes (22).

Our results showed that the ASES scale show statistically significant improvement between pre- and post-treatment in both groups. However, post-treatment ASES scale results for Group A were statistically significantly higher (89.25 ± 4.38) compared to Group B (60.25 ± 7.34) (P<0.001) The evidence of a significant increase when comparing the post-treatment evaluations to the baseline measurements of the passive ROMs for shoulder abduction, flexion, external rotation, and internal rotation (P<0.001), and by comparing both groups, we found a statistically significant higher ROM in Group A than Group B (P<0.001).

CONCLUSION

This study concluded that extracorporeal shock wave therapy is a successful treatment for shoulder dysfunction post mastectomy.

Limitation

The study had several limitations because of restrict inclusion criteria and sample size was relatively small and our patients needed longer time for following up.

Sources of funding: Funding institutions in the public, commercial, or nonprofit sectors did not award a specific grant for this research.

Conflicts of interest: There are no conflicts of interest, according to the authors.

REFERENCES


