Shockwave on Shoulder Pain and Limitations After Mastectomy

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Abstract

Background: Almost, prophylactic mastectomy carried out to treat mainly whom believed to be at high risk of breast cancer, unless there is post mastectomy complications might developed including lymphedema, limited shoulder mobility, as well neuropathic impairments. Up to date, benefits of extracorporeal shock wave therapy (ESWT) were postulated to relieve pain intensity due to insertional tendinopathy by provoking painful level of hyper-stimulation analgesia. Purpose: This study was conducted to investigate efficacy of shock wave on shoulder pain and limitations after mastectomy by measuring range of motion (ROM) using universal goniometer (UG) and pain intensity using visual analogue scale (VAS). Method: Forty women post mastectomy participants were randomly allocated into two equal groups in number; Group A: Twenty patients, whom had received ESWT followed by active shoulder exercises and routine medical treatment [NSAIDS], one session per week along 4 successive weeks. Group B: Twenty patients had received active shoulder exercises, plus routine medical treatment [NSAIDS] for 4 successive weeks. Evaluations of both groups were done at baseline and by the end of the study through UG and VAS. Result: This study showed a statistically significant increase in shoulder ROM and reduction in pain intensity in Group A; compared with Group B. Comparison between both groups, at baseline of this study revealed that there were statistically non-significant differences. By the end of this study, there was a significant increase in shoulder (flexion, abduction and external rotation) and decrease pain intensity in Group A compared with Group B post treatment. Conclusion: The present study concluded that the shock wave is a useful method in treating shoulder pain and limitation of range of motion post mastectomy.

Keywords: Mastectomy, Shoulder pain, Limitation of shoulder range of motion, Shock wave.

1. Introduction

Mastectomy as prophylactic localized surgical intervention carried out to remove frequently reported cancerous tissues,1 unless it results in restricted arm/shoulder mobility with 17% incidence, thus could cause arm/shoulder pain and connective tissue fibrosis.2 Post mastectomy complications might develop i.e., lymphedema, impaired shoulder mobility by up to 50% incidence, as well neuropathic impairments such as brachial plexopathy or plexus injuries those might develop chronic ache, pain and skeletal musculature weakness by 18-23% occurrence incidences, which have negative impact on quality of life.3 Almost, the long-term post mastectomy shoulder pain is relatively explained as a result of disturbed kinematics of shoulder complex.4

Novel convenient, non-invasive, feasible, safe and cost-effective therapeutic approach in form of shock wave therapy is a sequence of single sonic pulses characterized by high-energy supersonic jet that terminates in a bursting of energy similar to a mini-explosion (100 MPa), fast pressure rises (<10 ns) and short lifecycle (10 µs) are conveyed into a specific target area with the energy density in the range of 0.003-0.890 mJ/mm2 that could be utilized even for surgical pain management.5-6

ESWT utilizes a high peak pressure ranging from 5 to 130 Mpa, with a most common energy of 50 Mpa and a broad frequency of 14 Hz to 20 MHz, that aids revascularization and stimulate or reactivate the healing of connective tissues thereby relieving pain sense, promotes angiogenesis, increase perfusion in ischemic tissue, decreases inflammation, enhances cell differentiation and improving functions.7

Based on prior publications, main benefits of ESWT were explained due to direct mechanical forces resulted in maximal beneficial pulse energy concentrated at target point, where ESWT was applied; plus, indirect mechanical forces by cavitation, which creates negative effect or damage to underlying tissues.8

In addition, pain induced by ESWT is mediated mainly by the reduction of substance P in target tissues in conjunction with reduced synthesis of such molecule in dorsal root ganglia, as well due to selective unmyelinated nerve fibers destruction within focal zone underlying tissues.6 ESWT reverts the decrease of neuronal nitric oxide synthase (NNOS), basal nitric oxide (BNO) production and NO production induced by a mixture of lipopolysaccharides (LPS), interferon-(IFN-),

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plus tumour necrosis factor-α (TNF- α).5
Prior published trials had stated that ESWT could enhance early release of angiogenesis-mediating growth and proliferating factors including ENOS (endothelial nitric oxide synthase), VEGF (vessel endothelial growth factor) and PCNA (proliferating cell antinuclear antigen) those lead to improvement of blood supply and tissue regeneration.9-10
So that the current study was carried to investigate efficacy of Shock wave on shoulder pain and limitations after mastectomy by measuring ROM and pain using UG and VAS.

2. Subject, Material &Methods

Study Design

This study was designed as a Prospective, Pre/ Post-treatment, randomized controlled trial. After approval of the ethical committee of the Faculty of Physical Therapy, Cairo University- Egypt, the procedures of the present study were discussed thoroughly and all the participants were asked to sign a written informed consent.

Participants

Forty women post mastectomy participants allocated randomly into two groups (twenty patient per group), their age was > 38 years old, were selected randomly from both The Outpatient Clinics of Kasr El-Aini and Bahia Hospital. Participants were randomly assigned into two equal groups; Group A; Twenty patients, whom had received shock wave followed by active shoulder exercises and routine medical treatment [NSAIDS], one session per week along 4 successive weeks. Group B; Twenty patients had received active shoulder exercises, plus routine medical treatment [NSAIDS] for 4 successive weeks. Evaluations of both groups were done at baseline and by the end of the study through UG and VAS. Randomization were conducted using a computer-generated randomized table using SPSS program "version 25 for windows; SPSS Inc., Chicago, Illinois, USA". Each participant had one identification number that was used to assign participants into two equal groups in number (n=20), sequentially numbered index cards were secured in opaque envelopes. A researcher opened the sealed envelope and allocated the participants according to their groups.

Exclusion Criteria

All participants were excluded if had thrombosis, a positive history of shoulder impingement syndrome, had a life-threating disorders i.e., renal failure or myocardial infarction or whom had received other physical therapy treatment, chemotherapy or sharing in other clinical trial, also in case of suffering of any psychological problems, mental disorders or suffering from any disorder affects their cognitive capabilities.

3. Instruments

Assessment Instrument

Visual Analogue Scale (VAS)

it is a unidimensional measure of pain intensity. VAS has been widely used in diverse adult populations that is believed to range across a continuum of values and cannot easily be directly measured.11-12

Universal Goniometer (UG)

It is a 180 °or 360 ° protractor with one axis that joins two arms, one arm is movable around the axis or fulcrum of the protractor apparatus13 used to quantify baseline limitations of range of motion that has been shown to be valid and reliable.14

Therapeutic Instrument

Extracorporeal Shock Wave Device

It is (Beco ESWT, power 250 VA, frequency 1-15 Hz, Energy up to 4 bar &voltage 240V).[15]

Evaluating Procedures

History taking

Detailed medical history was taken from each participant in current clinical trials` groups before starting the study and was recorded in a data recording.

Specific Outcome Measures

Pain Intensity Threshold via VAS

VAS a self-reported pain measurement a widely utilized pain intensity assessment scale that has been shown to be valid and reliable. Each participant was instructed to sit in relaxed position then asked to mark the point on the line that exactly corresponded to her pain. 11-12

Shoulder ROM (Flexion, Abduction and External Rotation)

All the participants were assessed via UG to assess their shoulder ROM (flexion. abduction and external rotation), where UG`s axis of the goniometer be places at lateral arm and moving arm parallel to moving limb. In specific for shoulder internal rotation, participant was asked to relaxed in supine position, also the UG was positioned with the fulcrum placed at the olecranon, the stable arm horizontal or vertical, depending on the specific procedure, and on the moving arm along the forearm with processus styloideus ulnae as a reference point.16

Therapeutic procedures

ESWT Followed by active shoulder exercises (Group A)

Participant was lying supine and ESWT was applied directly to shoulder joint. Ultrasound gel was used as a coupling agent then applicator of ESWT was held perpendicular to the treatment surface. During the initial impulses, participants were instructed to adjust the applicator in order to feel the shock waves target the localized region of pain. Treatment impulses were 6000 extracorporeal shock wave impulses in 4 sessions over a period of four weeks [1500 extracorporeal shock wave impulses every session], plus noting shock wave transducer position was changed after every 500 pulses to scan painful area. As well, the starting energy density was 0.2 mJ /mm². 0.5 mJouls/mm² was added in each week (0.25 mJouls/mm² in week two, 0.3 mJouls/mm² in week

three, and 0.35 mJouls/mm² in week four) along 5-15 minutes depend on patient tolerability.[15]

Active Shoulder Exercises Training (Group B)

participants had received active exercises of shoulder (flexion, abduction and external rotation), as home program daily in addition to routine medical treatment [NSAIDS].

4. Statistical Analysis

SPSS version 25 for windows (IBM SPSS, Chicago, IL, USA) was used to conduct the analysis of this study. Normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups.17 Mixed MANOVA was conducted to investigate the effect of treatment on VAS and shoulder ROM. Post-hoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).18

5. Results

1. Subject characteristics

2. Forty patients participated in this study. Patients were subdivided into two groups, twenty patients in each group. The mean ± SD age of study group was 51.5 ± 8.53 years, with maximum value of 64 years and minimum value of 40 years. The mean ± SD age of control group was 50.7 ± 8.24 years, with maximum value of 66 years and minimum value of 38 years. There was no significance difference between groups in the mean age values ($p = 0.76$).

3. Effect of treatment on VAS and shoulder ROM

4. Mixed MANOVA revealed a significant interaction effect of treatment and time ($F = 19.3$, $p = 0.001$). There was a significant main effect of treatment ($F = 4.07$, $p = 0.008$). There was a significant main effect time ($F = 80.18$, $p = 0.001$).

5. Within group comparison

6. There was a significant decrease in VAS and a significant increase in shoulder ROM post treatment in both groups compared with that pretreatment ($p > 0.001$). The percent of change in VAS, flexion. abduction and external rotation of study group was 34.17, 13.25, 20.02 and 26.71% respectively and that in control group was 13.22, 3.97, 7.39 and 13.84% respectively. (Table 1).

7. Between group comparison

8. There was no significant difference between groups pretreatment ($p > 0.05$). Comparison between groups post treatment revealed a significant decrease in VAS of study group compared with that of control group ($p < 0.001$). There was a significant increase in flexion ($p = 0.02$), abduction ($p = 0.002$) and external rotation ($p = 0.02$) of study group compared with that of control group post treatment. (Table 1).

Table (1): Mean VAS, shoulder flexion, abduction and external rotation ROM pre and post treatment of both study and control groups

	Pre treatment	Post treatment			
	Mean ±SD	Mean ±SD	MD	% Change	P value
VAS					
Study group	6 ± 0.85	3.95 ± 1.23	2.05	34.17	0.001
Control group	6.05 ± 0.88	5.25 ± 0.96	0.8	13.22	0.001
MD	-0.05	-1.3			
	p = 0.85	p = 0.001			
ROM (degrees)					
Flexion					
Study group	129.1 ± 16.53	146.2 ± 15.82	-17.1	13.25	0.001
Control group	129.75 ± 13.71	134.9 ± 15.1	-5.15	3.97	0.001
MD	-0.65	11.3			
	p = 0.89	p = 0.02			
Abduction					
Study group	109.75 ± 14.09	131.75 ± 15.32	-22	20.05	0.001
Control group	108.25 ± 13.21	116.25 ± 14.8	-8	7.39	0.001
MD	1.5	15.5			
	p = 0.73	p = 0.002			
External rotation					
Study group	40.25 ± 7.34	51 ± 9.94	-10.75	26.71	0.001
Control group	38.65 ± 7.36	44 ± 8.52	-5.35	13.84	0.001
MD	1.6	7			
	p = 0.49	p = 0.02			

SD: Standard deviation; MD: Mean difference; p value: Probability value

6. Discussion

Clinically, mastectomy results in restricted arm/shoulder mobility leads to arm/shoulder pain and fibrosis.2 Recently, ESWT as non-invasive therapeutic approach for post mastectomy limited mobility painful shoulder has receiving attention as a potential therapeutic option in line to improve

shoulder function, decrease shoulder pain and improve shoulder limitations and strength.19-21

Regarding baseline evaluation, no significant difference in VAS, flexion, abduction and external rotation ROM between study and control groups pretreatment (P values were 0.85, 0.85, 0.73 and 0.49, respectively).

Current study was based on that residual effects of surgical scarring and fibrosis post mastectomy could affect the mechanics of the shoulder region through tethering of soft tissue or pain-inhibited movement.22

Regarding overall evaluation, there were a significant decrease "-1.3, -17.1 degrees and the percent of change was 13.25%, -22 degrees and the percent of change was 20.05% and -10.75 degrees and the percent of change was 26.71%, respectively" in the VAS, flexion, abduction and external rotation ROM of study group compared with control group post treatment ($p = 0.001$). As well, regarding treatment effect there was a significant increase by "11.3, 15.5 and 7 degrees, respectively" in flexion, abduction and external rotation ROM of study group compared with that of control group post treatment ($p = 0.02$)

Several compensatory mechanisms have been proposed to explain ESWT was presented as a new way to treat frozen shoulder, improving shoulder pain and functions in frozen shoulder. By applying ESWT on shoulder Consisting of 2000 shock wave pulses fired with a repetition frequency of 2 pulses per second. Energy level or intensity was set at a tolerable level by patient (0.2mJ/mm2). The entire treatment lasted 15min per session and was usually performed without local anesthetic drugs. All subjects received 3 sessions of ESWT on the first, 14th and 28th days.19

Current study revealed results were supported by findings that ensured that ESWT proved to be efficient and safe in treatment of shoulder pathologies through showing significant declines in their degree of pain intensities as measured by VAS score and statistically significant increases in their flexion and external rotation ROM by using 1000 shocks with frequency 4 Hz.20

Post treatment, both groups showed a variant increase in range of motion of (flexion, abduction and external rotation) and improvement in pain according to universal goniometer and vas, but statistically significant improvement difference was recorded between the two groups in favor of the study group.

Current study revealed results were supported with recent published and stated that ESWT is a simple, effective and noninvasive alternative for the treatment of rotator cuff lesions with shoulder stiffness. The benefits of ESWT on the functional outcome could be gained within six up to twelve months of treatment.21

The results of the current study supported by enormous number of scientific research those confirm that shock wave is a beneficial therapeutic modality in shoulder pain and limitation of range of motion post mastectomy

7. Conclusion

Based on current study revealed results and in correlation with prior clinical trials could advise Shock wave therapy followed by active shoulder exercises in addition of routine medical treatment is better than active shoulder exercises in addition to routine medical treatment, only to significantly improve patients' functional capacity as evidenced by improving range of motion and decreasing pain through universal goniometer and visual analogue scale methods of assessment

Limitation of this study

This study did not investigate the long-term effects of the used treatment.

8. Recommendations

Further studies should be conducted for comparing efficacy of ESWT among highly selected populations with other physical therapy modalities in the treatment of whom have undergone mastectomy surgeries with increase sample size.

Conflict of interest

The authors confirmed that this article content has no conflict of interest.

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