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Does Extracorporeal Shockwave Therapy Replace Joint Mobilization for the treatment of Subacromial Impingement

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Subacromial impingement is one of the most common shoulder dysfunctions in clinical practice. Extracorporeal shockwave (ESWT) is noninvasive therapeutic modality has evolved as option for management of different musculoskeletal disorders. The aim of this study was to compare between the effectiveness of extracorporeal shockwave and joint mobilization in the treatment of sub acromial impingement. The study was designed as a randomized controlled trial. Sixty patients with subacromial impingement were randomly assigned to an ESWT group (n=20), mobilization group (n=20), and control group (n=20). The ESWT intervention consisted of one session weekly for 4 weeks with total of 6000 impulses (energy flux density, 0.11 mJ /mm^2). The joint mobilization intervention consisted of three sessions per week for up to 6 weeks. Outcome measures were the visual analog scale (VAS), shoulder disability questioner (SDQ), and active range of motion (ROM) of the shoulder joint. Analyses of variance test was used to determine differences between groups for all measured parameters. Paired t-test was used to compare between the pre- and post-treatment values within groups.For the 60 study participants (28 women and 32 men; mean age=44.1±7) years there were no between-group differences at baseline in VAS, SDQ score, and ROM of the shoulder joint. At the end of the 6-week of intervention, subjects in ESWT and mobilization groups experienced significant decrease in pain , improve in shoulder function, and increased ROM than those in the control group ($p < 0.05$) . Pain and shoulder function were significantly improved in ESWT group compared with the mobilization group, while shoulder ROM was more significantly increased in the mobilization group than in the ESWT group. The results suggest that ESWT could be more effective treatment modality for management of subacromial impingement than joint mobilization when pain and functional disability are the main patient complains.

Keywords: Extracorporeal Shockwave Therapy - Mobilization - Subacromial Impingement

INTRODUCTION

Subacromial impingement syndrome (SIS) is the most frequent encountered musculoskeletal disorder in general practice .It was estimated that the cumulative incidence of shoulder impairment accounted for 23.1/1000 patients (Bot et al., 2005). It has been suggested that majority of people with impingement syndrome who are younger than 60 years of age relate their symptoms to occupational or athletic activities that involve frequent overhead use of the arm (Alizadehkhaiyat et al., 2018). Several factors

have been suggested to contribute to the development of impingement syndrome. These factors include abnormal acromial morphology; aberrant kinematic patterns due to poor rotator cuff or scapular muscle function, capsular abnormalities poor posture, and overuse secondary to repetitive eccentric loading or sustained use of the arm above 90 degrees of elevation (Conroy and Hayes 1998). The spectrum of subacromial pathology is extensive and includes rotator cuff tendinopathy, partial thickness rotator tear, calcific tendinitis, and acute or chronic subacromial bursitis(Koester et al., 2005).

While many treatments have been employed in the management of shoulder impingement syndromes, few have been proven to be effective in randomized controlled trials (Koester et al., 2005). Corticosteroid injections, non-steroid anti-inflammatory drugs, physical therapy modalities, strength and stretching exercises have been listed as non-surgical approaches for subacromial impingement syndrome (Yanagisawa et al., 2003). One of the treatment options in shoulder impingement syndrome is manual therapy techniques including deep friction massage and joint mobilization techniques (Desmeules et al., 2003). The main goals of manual therapy of subacromial impingement are to reduce subacromial inflammation, allow healing and strengthening of a dysfunctional rotator cuff and restore pain-free shoulder function (Morrison et al., 2000) .

Extracorporeal shockwave therapy (ESWT), originally invented in the early 1980s to destroy kidney stones, are recommended nowadays as a second line-therapy with limited evidence of effectiveness before surgery (Daecke et al., 2002). The analgesic effect of shockwave therapy along with its ability to disintegrate calcific deposits and favorably alter osseous and tendinous biology, coupled with demonstrated safety and noninvasiveness, made it uniquely suited to the treatment of ubiquitous orthopedic disorders in the out-patient setting (Schaden et al., 2007). The safety and efficacy of shockwave therapy in the treatment of common lifestyle-limiting musculoskeletal conditions have been supported by clinical trials, some of these conditions include plantar fasciitis, lateral epicondylitis of the elbow, and calcific tendonitis of the shoulder and more recently for delayed unions or non-unions of bone (Spacca et al., 2005, Kudo et al., 2006).

The exact mechanism of shockwaves remains unknown. Some studies demonstrated that ESWT causes subperiosteal callus formation by creating small fractures on the cortex (decortication) (Ikeda et al., 1999). Other studies showed that ESWT stimulates expression of growth factors including vascular endothelial growth factor (VEGF) and bone morphogenetic protein (BMP) that, in turn, improve blood supply and cell proliferation and eventual tissue regeneration(Chen et al., 2004) .

Several previous studies evaluate the effects of shockwave therapy versus sham therapy and conservative physical therapy modalities in subacromial impingement (Schmitt et al., 2002, Speed et al., 2002) , but comparison between the therapeutic effects of ESWT versus joint mobilization in the treatment of patients with subacromial impingement is lacking in the literature. So the aim of this trial was to compare the effectiveness of two physical therapy treatment approaches for impingement syndrome, either by ESWT or by joint mobilization techniques after 6 weeks of treatment.

MATERIALS AND METHODS

The study was designed as a randomized controlled trial to compare between the effectiveness of extracorporeal shockwave and joint mobilization in the treatment of subacromial impingement. The data were collected between 2016 and 2017 at the Physical Med and Rehabilitation Center for Armed Forces in El Helmia after the approval of the center Ethical Committee. Participants are assigned at random to an ESWT, mobilization or control group.

Subjects

60 patients (32 males and 28 females) diagnosed with SIS by referring physician, aged from 30-55 years were selected from outpatient clinic of the Physical Med and Rehabilitation Center for Armed Forces in El Helmia. All patient signed the informed consent before engagement in the study.

Eligibility criteria

Inclusion criteria: (1) age between 30 and 55 years, (2) symptoms for more than three months, (3) main complaints in the glenohumeral joint region or the proximal arm, (4) one of the following signs indicating SIS: Neer impingement test, Hawkins-Kennedy impingement test, painful arc with active abduction or flexion, (5) pain with one of the following resistance tests: external rotation, internal rotation, abduction, or flexion.

Exclusion criteria: (1) coagulation disturbance (2) primary scapulothoracic dysfunction due to paresis, (3) diagnosed instability or previous history of dislocation, (4) adhesive capsulitis (frozen shoulder), (5) unsuccessful prior ESWT(6) substantial loss of active shoulder function, (7) shoulder surgery in the last 12 months on the involved side, (8) reproduction of symptoms with active or passive cervical movements, (9) nervous system involvement with sensory and muscular deficit, (10) inflammatory joint disease (e.g. rheumatoid arthritis), (11) diabetes mellitus,(12) pregnancy.

Sample size calculation

Prior to initiating the study, a sample size of 70 subjects was calculated to provide 80% power to detect differences of 10mm on visual analogue scale between the 3 groups of interest with 15% SD at 95% CI . Calculations were based on our judgment of what are clinically meaningful differences and variability estimates from previous studies on subjects without shoulder impairment

Randomization and allocation

After informed consent and baseline assessment participants were allocated to either ESWT, Mobilization or, control group. Randomization was performed using sealed, randomly filled envelopes describing the treatment groups (figure 1).To guarantee allocation concealment, therapists were informed about allocation after the participant completed all baseline measurements and gave informed consent, prior to first treatment.

The study was designed as a randomized controlled trial to compare between the effectiveness of extracorporeal shockwave and joint mobilization in the treatment of subacromial impingement. The data were collected between 2016 and 2017 at the Physical Med and Rehabilitation Center for Armed Forces in El Helmia after the approval of the center Ethical Committee..

Intervention

Participants were requested not to make use of other treatment options and not to change their medication intake during the intervention phase. However, due to ethical considerations the use of analgesics and non-steroidal anti-inflammatory drugs were permitted and recorded in the medical sheet.

ESWT application

Participants in ESWT group received shockwave therapy. It was provided using Chattanooga intellect RPW. It comprises a control system and a shockwave applicator connected to the control system by means of an applicator cable, and a medical air compressor. The compressor generates a pneumatic energy that is used to accelerate a projectile inside the applicator. When the projectile strikes the applicator, a shockwave is generated and radically spreads from the tip of the applicator to the target zone .An optional foot switch can also connected.

The treatment was administered once a week for 4 weeks, treating the most tender points. The tender points were identified through a patient tolerance as a following: (1) insertion of supraspinatus tendon,(2) dorsolaterally below acromion, and (3) a maximum of 3 trigger points in the rotator cuff muscles)(Gerdesmeyer, Wagenpfeil et al., 2003) . The frequency applied was 10 Hz, from 1500 pulses per session, with pressure between 2.5 and 4.0 bar depending on the patient's tolerance. The energy flux density was 0.11 mJ /mm^2 and a fixed impulse time of 2 milliseconds. Treatment was conducted for 4 sessions with one week interval. A transmission gel was applied between the applicator and the treated part to optimize shockwave transmission to the patient. The applicator was slowly moved around the point of maximal tenderness without local anesthesia.

Mobilization technique

Participants in the mobilization group received shoulder joint mobilizations started with posterior gliding grade III/IV. As patients with subacromial impingement may present with the humeral head sitting more anteriorly in the glenoid fossa, this technique helping not only for pain reduction, but also for improving pain free ROM. The therapist provides slight distraction of the humeral head while applying pressure on the anterior surface of the humeral head in a posterolateral direction, feeling for resistance. Posterior glide allow the posterior capsule to stretch and the humeral head to rest more posteriorly than its previous resting position (Yiasemides et al., 2011).

Inferior glide of the humerus was performed with the shoulder in approximately 90° of abduction aimed at improvement of the extensibility of the axillary recess. Both hands

were held close to the humeral head to work with a short-

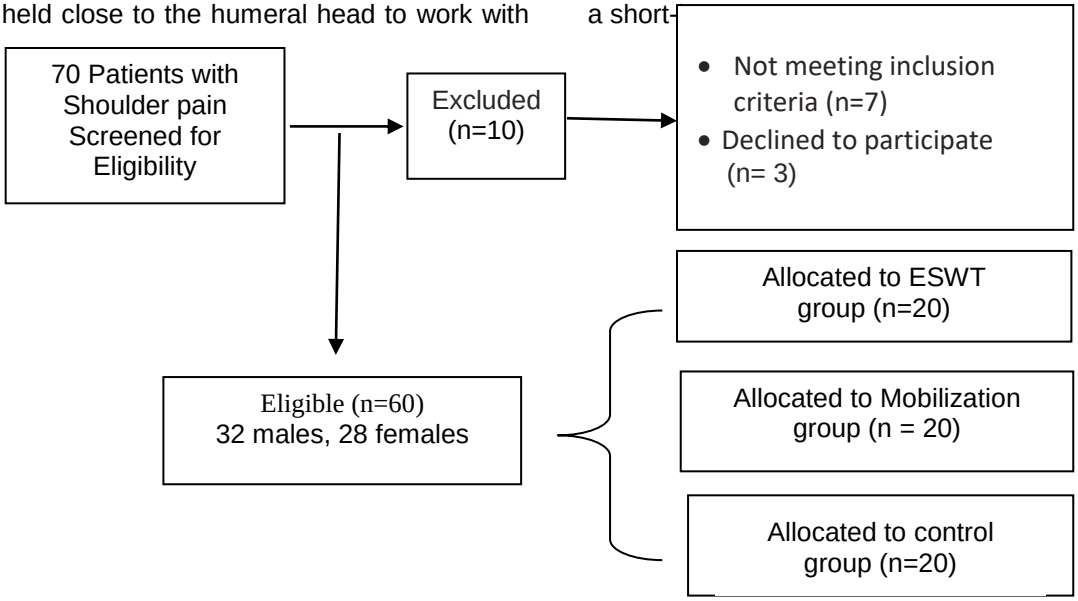

Figure.1. Flow diagram showing subject recruitment and retention

Oscillatory movements in the caudal, lateral, and anterior directions were used. The anterior gliding mobilization technique was done with the patient lying prone with the glenohumeral joint abducted 90^{o} degree in the scapular plane, the applied force was in the anterolateral direction to increase extension and external rotation ROM.

Each mobilization was applied for 30 seconds at a rate of approximately one mobilization every 1 to 2 seconds, followed by a 30-second rest. The 30-second mobilization and resting sessions were repeated 2 additional times for a total of 3 sets of 30-second mobilizations. The force and amplitude of the treatment movements varied, but eventually all experimental subjects were able to tolerate grade IV oscillations (small amplitude motions at the end of the range of motion) without significant discomfort. Generally, in the early sessions gliding and distractive mobilization techniques were performed with the joint near its neutral position, progressing in the later sessions to mobilization toward the end of the range of motion.

Participants in the control group received patient education on postural awareness and limitation of overhead activities by the referring physician during his/her initial examination session without any physical therapy intervention.

Baseline assessment

After informed consent the following baseline measurements were carried out. The primary outcome measures for this study were shoulder pain, shoulder functional disability and active ROM of the shoulder joint.

Pain

The VAS was used to measure pain on a 10-cm horizontal axis between a left endpoint of “no shoulder pain” and a right endpoint of “worst pain ever.” The distance is measured, and pain is recorded on a 10-point scale. the VAS has been shown to have very good test-retest reliability (intraclass correlation coefficient (ICC >0.90) (Ong and Seymour 2004) .

Shoulder Disability Questionnaire (SDQ)

The SDQ is a 16-item measure for functional status limitation in patients with shoulder disorders. It covers 16 items each with 3 answering options—“yes,” “no,” and “not applicable .The score is calculated by multiplying the yes/no ratio by 100.”. The score ranges from a minimum of 0 points (no functional limitation) to a maximum of 100 points (affirmative answer to all applicable items). The validity of scores for the SDQ has been established along with those of other shoulder questionnaires (van der Windt et al. ,1998) .

Shoulder active ROM

Active ROM of the shoulder was measured in all planes with a conventional goniometer in accordance with the guidelines of the American Academy of Orthopaedic Surgeons, while the patients were lying supine pre- and post-treatment. Shoulder flexion was assessed in the sagittal plane with the arm at the side and the hand pronated, while shoulder abduction was measured in the frontal plane with the arm at the side and shoulder externally rotated to obtain maximum abduction. Shoulder external and internal rotation were measured in the transverse plane while the arm was abducted to 90◦, the elbow flexed to 90◦ the hand pronated and forearm perpendicular to the floor. All measurements were rounded off to the nearest 5 degrees, as is common in research practice.

Data Analysis

The data was analyzed using SPSS for Windows software, version 18.0 (SPSS, Inc., Chicago, IL). Statistical significance was set at $P = 0.05$. Paired *t*-tests were performed to detect any differences between baseline and post-treatment values within groups including: VAS pain score, shoulder disability score and shoulder ROM measurements. Analyses of variance test was used to determine differences between groups for all measured parameters.

RESULTS

60 patients with subacromial impingement, aged from (30 to 55) years who fulfilled the inclusion criteria agreed to participate in the study and were randomly allocated to either the ESWT, mobilization or control groups. Demographic characteristics and baseline measurement of the three groups before the treatment are shown in (Table 1). There was no significant difference between the three groups regarding age, weight, symptoms duration and the baseline measurements (P**>**0.05).

Comparison of the pre- and post-treatment values of the VAS score revealed a highly significant pain reduction in the ESWT and mobilization groups with no significant change in the control group (p=0.209). Post-treatment measurement comparison showed a significant difference between groups in favour of ESWT group table 2.

The analysis of the functional disability results revealed that subjects in both groups (ESWT& mobilization) experienced significant increases in shoulder function, but there was significantly more improvement in the ESWT group compared to the mobilization group table 3.

Analysis of post treatment outcomes regarding shoulder range of motion revealed that active ROM of the shoulder joint in flexion, abduction and external rotation was significantly improved in mobilization group than ESWT group table 4.

Table 1.Demographic data and baseline assessment of 60 Patients

Characteristics	ESWT group (n=20) mean ±SD	Mobilization group (n=20) mean ±SD	Control group (n=20) mean ±SD	F-value	P-value
Age (year)	45.8 ±7.4	41.5 ±5.8	45.2±7.3	2.25	0.114
Weight (kg)	83.6 ±6.8	81.05±5.6	78.1±10.6	2.82	0.100
Symptom duration (month)	12.8±3.4	12.2±2.7	14.1±3.2	1.87	0.163
Pain (VAS)	7.65±0.87	7.2±0.76	7.2±0.63	2.07	0.136
Functional disability (SDQ)	66.45±6.68	66.75±5.45	66±5.6	0.08	0.923
Shoulder ROM					
Flexion	99.05±19.4	91.1±19.9	86.9±16.3	2.19	0.121
Abduction	73.9±13.7	79.2±16.1	83.6±13.9	2.53	0.088
Ext. rot.	17.5±7.8	17.45±5.5	20.25±7.5	1.015	0.369

*significant SD: Standard Deviation, P: Probability Ext. Rot.: External Rotation

Table 2.Statistical analysis of VAS (pain) within each group and between groups

VAS	ESWT group (n=20) mean ±SD	Mobilization group (n=20) mean ±SD	Control group (n=20) mean ±SD	F-value	P- value
Pre	7.6 ±0.87	7.2±0.7	7.25±0.6	2.07	0.136
Post	4.6±0.98	6±0.91	6.95±0.99	28.4	0.001*
t-value	16.8	4.18	1.3		
P- Value	0.006*	0.001*	0.209		

VAS: visual analogue scale *significant

Table 3.Statistical analysis of SDQ (functional disability) within each group and between groups

SDQ	ESWT group (n=20) mean ±SD	Mobilization group (n=20) mean ±SD	Control group (n=20) mean ±SD	F-value	P-value
Pre	66.4 ±6.6	66.7±5.4	66.6±5.6	0.08	0.923
Post	53.9±7.7	61.7±9.2	65.6± 5.1	12.52	0.001*
t-value	8.67	2.92	0.64		
P- Value	0.001*	0.009*	0.524		

SDQ: shoulder disability questioner *significant

Table 4.Statistical analysis of shoulder ROM within each group and between groups

Variables	ESWT group (n=20) mean ±SD	Mobilization group (n=20) mean ±SD	Control group(n=20) mean ±SD	F-value	P-Value
Pre **Shoulder flexion** **Post**	99.05 ±19.42 111±21.25	91.1±19.97 115.35±26.04	86.9±16.3 85.25±15.43	2.19 11.60	0.121 0.001*
T- value	-9.187	-9.20	1.304		
P- value	0.001*	0.009*	0.208		
Pre Shoulder abductionPost	73.9 ± 13.74 94.30 ± 17.18	79.20± 16.10 112.45± 30.02	83.60±13.92 85.50±15.38	2.2 7.90	0.12 0.001*
T- value	-5.05	-5.26	-0.521		
P- Value	0.001	0.002	0.60		
PreShoulder Ext. Rot. Post	17.55± 7.81 19.85± 6.51	17.45±5.58 24.9 ±6.58	20.25±7.54 20.50±7.26	1.015 3.267	0.369 0.045*
T- value	-2.187	-4.033	-1.10		
P- Value	0.041	0.001	0.330		

* significant SD: Standard Deviation, P: Probability Ext. Rot.: External Rotation

DISCUSSION

Extracorporeal shockwave therapy has been used for the management patients with tendinitis and subacromial shoulder pain when conventional physical therapy was not effective in relieving pain and other symptoms(Gerdesmeyer et al., 2003). The main goals for using of ESWT for these conditions were based on stimulation of soft tissue healing by local hyperemia, neovascularization, reduction of calcification, inhibition of pain receptors and/or denervation to achieve pain relief and persistent healing of chronic inflammatory processes (Maier et al., 2002) .

This study was designed to compare between the clinical effectiveness of ESWT and joint mobilization in treating subacromial impingements. The results of the current study demonstrated that subjects in ESWT and mobilization groups experienced significant decrease in pain, improve in shoulder function, and increased shoulder active ROM than those in the control group. Pain and shoulder function were significantly improved in ESWT group compared with the mobilization group, while shoulder ROM was more significantly increased in the mobilization group than in the ESWT group.

The reduction of pain and improvement of shoulder function in the ESWT group could be explained as follows: reduce the number of calcitonin gene-related peptide (CGRP) and substance P immune reactive neurons in the dorsal root ganglia. These are two substances involved in pain perception. CGRP is a neuropeptide that is known for its major vasodilatation potency and is found in sensory nerves while substance P is present in both unmyelinated C-fibers and of lightly myelinated A-delta nerve fibers and is released at central and peripheral terminals of sensory nociceptive neurons after stimulation (Takahashi et al., 2003, Hausdorf et al., 2008). Richardson revealed that release of these substances from primary sensory nerve terminals may contribution the pathogenesis of inflammation, without apparent infiltration of inflammatory cell called neurogenic inflammation(Richardson and Vasko 2002) .

Recent experimental study suggested that ESWT induce a selective destruction of small unmyelinated nerve fibers within its focal zone. Importantly, these fibers are known to be responsible for throbbing chronic pain leading to long-term analgesia following shockwave application(Hausdorf et al., 2008) .

The role of ESWT in resorption of the calcification in the tendon and reactive hyper vascularization has been proposed for improved shoulder function in calcific tendinopathy of the shoulder joint (Spindler et al., 1998). it has been suggested that that pain arising from tendinopathy is due to hypovascular change with a degenerative process with or without trauma ESWT induce controlled microdestruction of avascular or minimally vascular tissues, which encourage revascularization, and improving tissue regeneration (Loew et al., 1995) .

The results of the current study come in contact with Cacchio et al, who suggest that the use of radial SWT for the management of calcific tendinitis of the shoulder is safe and effective, leading to a significant reduction in pain and improvement of shoulder function after 4 weeks, without adverse effects (Cacchio et al., 2006). Also Schofer et al., compared between the effect of high-energy ESWT and low-energy ESWT in treatment of rotator cuff tendinopathy the results demonstrated that both high energy and low energy ESWT appeared to provide a beneficial effect on shoulder pain and function nitrating patients with tendinopathy(Schofer et al., 2009) . Moreover Haake et al demonstrated that ESWT appears to be at least equivalent to radiotherapy in treating chronic supraspinatus tendinitis syndrome and can avoid a dose of radiation for patients and staff (Haake et al., 2001) .One of the systematic review investigate the effect of ESWT in calcific tendinitis of shoulder concluded that ESWT has been postulated to be an alternative, minimally invasive, less traumatic treatment option for treating calcific tendinitis of the shoulder before surgery (Mouzopoulos et al., 2007).

The results did not agree with Schmitt who revealed that low-energy ESWT in the treatment of tendinitis of the supraspinatus is time-consuming, expensive and probably ineffective compared with subacromial injections(Schmitt et al., 2001) . In this study neither the applied dose nor the number of treatments was standardized also the method of assessment was not uniform, nor was there a control group. On potential weakness in this work was absence of diagnostic criteria neither radiographic or magnetic imaging However, researchers conclude that a curved or hooked acromion observed on radiographs or magnetic resonance images is not a primary cause of shoulder impingement syndrome(Mayerhoefer et al., 2009). also lack of a cost-benefit analysis and follow up period were limiting factors of this study.

CONCLUSION

The results of this study provide evidence that ESWT could be more effective treatment modality for management of subacromial impingement than joint mobilization when pain and functional disability are the main patient complains.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare in this study.

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AUTHOR CONTRIBUTIONS

All authors contributed equally in all parts of this study. All authors read and approved the final version.

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