A Preliminary Study on the Effect of Low Energy Extracorporeal Shock Wave Therapy as a Treatment for Shoulder Adhesive Capsulitis in Hasan Sadikin Hospital Bandung, Indonesia

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Abstract: Adhesive capsulitis or frozen shoulder describes the common shoulder condition characterized by painful and limited active and passive range of motion. Extracorporeal shock wave therapy (ESWT) suggested as alternative treatment for adhesive capsulitis. Aim of this study was to determine the effect of low energy rESWT on adhesive capsulitis related to shoulder pain, shoulder range of motion, and function of the shoulder joint. The study design was an interventional, experimental study. A series of single-case studies was undertaken with patients shoulder adhesive capsulitis who came to the physical medicine and rehabilitation department Hasan Sadikin Hospital. Each patient received four weeks applications of low energy rESWT, 1 week apart. Outcome measure using NRS, ROM and DASH questionnaire. Result: Five patient, 4 Female and 1 Male were included, with mean age of patient is 50,60 ± 2,97 years old, mean length of symptoms 12 ± 6,96 month. Pain intensity, passive shoulder range of motions, and functional outcome are improved after 4 weeks intervention rESWT($p<0,05$). The low energy rESWT resulted in significant clinical and statistical improvement pain, passive shoulder ROM and functional outcomes in patients with shoulder adhesive capsulitis. Low energy rESWT as effective treatment alternative in shoulder adhesive capsulitis.

1 INTRODUCTION

Adhesive capsulitis or frozen shoulder describes the common shoulder condition characterized by painful and limited active and passive range of motion. The etiology of frozen shoulder remains unclear; however, patients typically demonstrate a characteristic history, clinical presentations, and recovery. Frozen shoulder is reported to affect 2% to 5% of the general population. Individuals with primary frozen shoulder are commonly between 40 and 65 years old, and the incidence appears higher in females than males (Kelley et al. 2009). More than 50% of frozen shoulder patients still have sequelae of symptoms after years of undergoing therapy, resulting in decreased quality of life of the patient (Guiloff et al. 2015).

Extracorporeal Shock Wave Therapy (ESWT) is defined as an acoustic wave characterized by high pressure peaks (100 MPa), rapid pressure increase with rise times of less than <10 nsec, shorter life cycle less than 10 ms, and energy density range of 0.003 – 0.890 mJ/mm (Gerdesmeyer et al. 2003).

Radial ESWT is a pneumatic type shock wave, producing low energy to medium compared with traditional focused ESWT and lower penetration depth than fESWT (3 cm vs 12 cm). This shock wave will be focused at the tip of the applicator without having to focus energy to the target point. Systematic review studies and meta-analyses reported rESWT has better result compared to fESWT in patients with plantar fasciitis because the result has a larger therapeutic area, so focusing therapy becomes less important, does not require local anesthesia and is more affordable (Chang et al. 2012).

Several studies have shown that ESWT is a relatively non invasive therapeutic modality with proven effectiveness, convenience and safety of the therapy of musculoskeletal problems (Ioppolo et al.

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2014). Extracorporeal shock wave therapy has been suggested as an alternative treatment for refractory shoulder pain due to calcific or noncalcific tendinitis and may be an alternative to expensive and risky surgical interventions (Bannuru et al. 2013). Recent studies show the use of ESWT has been suggested for the treatment of adhesive capsulitis (Vahdatpour et al. 2018).

The main purpose of the adhesive capsulitis treatment is to reduce pain, increase the range of joint motion and improve the function of the shoulder. Therapeutic effect of ESWT is to help revascularization, stimulation, bone reactivation and healing of connective tissues, which will lower the pain and improve shoulder joint function.

Shockwave modality uses sound waves of high or low energy that impart rapid fluctuations of pressure to tissues. The degree of energy imparted to the tissues is measured as energy flux density (EFD). There are many manufacturers of ESWT devices. Shockwave therapy is usually classified as high, medium, or low energy, according to the EFD administered. Although there is no consensus on the threshold values, a commonly used grouping defines EFD 0.08 to less than 0.27 mJ/ mm^2 as low energy, 0.28 to less than 0.59 mJ/mm^2 as medium energy, and more than 0.60 mJ/mm^2 as high energy (Speed 2004).

Several studies have been conducted to observe the effects of low dose and high dose rESWT in patients with shoulder pathology. Low dose rESWT does not reduce pain or improve function compared with placebo treatment in patients with chronic tendinitis of the rotator cuff (Kolk et al. 2013). Systematic review show that high energy fESWT is more effective than low energy fESWT for improving pain and shoulder function in chronic calcific shoulder tendinitis (no similar effects were seen in noncalcific tendinitis) and can result in the complete resolution of calcifications (Bannuru et al. 2013). Studies that conducted in adhesive capsulitis patients reported more effective responses with higher energy and proper session intervals in patients with adhesive capsulitis, hematomas as adverse event was reported in this study (Hussein et al. 2015).

Adverse effects of ESWT were dose dependent, patients who received high or medium energy ESWT reported more adverse events than those who received low energy ESWT. The most commonly reported adverse events related to ESWT were temporary increase acute pain and local reactions, such as swelling, local erythema, petechiae, small bruises and hematomas. No serious side effects have been reported (Bannuru et al. 2013).

The aim of this study was to determine the effect of low energy rESWT in adhesive capsulitis patient related to shoulder pain, shoulder range of motion, and function of the shoulder joint.

2 METHODS

The study design was an interventional, experimental study. A series of single case studies (n=5) was undertaken with patients shoulder adhesive capsulitis who visited the outpatient clinic of Physical Medicine and Rehabilitation Department Hasan Sadikin Hospital. The participants received oral and written information about the study and were informed of the potential risks of treatment. Written informed consent was obtained from all subjects before the baseline evaluation. Ethical clearence was given by the Health Research Ethic Committee Hasan Sadikin General Hospital.

The inclusion criteria were patients 40 - 65 years with shoulder pain and restriction in ROM in at least three directions, (i.e. flexion, abduction, external rotation, and internal rotation) for a duration of at least 6 months. Exclusion criteria were history of shoulder fracture, shoulder dislocation or subluxation, previous surgery on the shoulder, pre-rupture tendon or tendon rupture in the shoulder cancer, glenohumeral or acromioclavicular arthritis, presence of severe osteoporosis, inflammatory disorders, pulmonary diseases, bleeding disorders, pregnancy, any neuromuscular disorders, implanted pacemaker and unwillingness to participate in the study.

The rESWT was administered by the same experienced trained doctor with the EMS Swiss Dolorclast Smart20® (EMS Electro Medical Systems Corporation, Dallas, TX, USA).

Each patient received four applications of rESWT, 1 week apart, with 2000 impulses per session. The air pressure of the device was set to 2.5 bars, frequency of 8 Hz, energy flux density (EFD) 0.11 mJ/mm^2, and the impulses were applied with a 15 mm applicator.

The shock waves were delivered to two separate locations per session with the coupling gel. The first location was applied 1000 impulses in a posterior-to-anterior direction on the posterior side of the shoulder joint located beneath the lateral border of the scapular spine. The second location was applied remaining 1000 impulses of the total 2000 impulses per session in an anterior-to-posterior direction of the anterior shoulder joint, was about one finger breadth lateral to the coracoid process (Hussein et al. 2015) (Vahdatpour et al. 2018).

The outcome measure consists of pain intensity during rest and activity over the past 24 hr was assessed on Numeric rating Scale (NRS), the involved shoulder passive flexion abduction and passive external internal rotation were measured by a goniometer, function that measured by the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire which has been validated in Indonesian language (Magetsari 2010). Home-based exercise that performed by patients, incidence of painful activity or other adverse events are documented. All outcome measures were taken at baseline before the treatment, after 4 weeks (at the end of treatment) by experienced trained doctor.

The obtained data were analyses were performed using The Statistical Package for Social Sciences (SPSS) software ver.18.0 (SPSS Inc., Chicago, IL, USA). A paired t-test was conducted to determine statistical differences in the variables between the pre and post treatment. Values are presented as mean ± standard deviation for data with a normal distribution, and $p<0.05$ was considered statistically significant.

3 RESULTS

Five patients with shoulder adhesive capsulitis who met the selection criteria were recruited. Subject more likely to be female, with mean age of patients is 50,6 years old and mean length of symptoms 12 month (Table 1). All the subjects complete the intervention phase.

Table 1: Subject demographic characteristics.

No	Variable	n = 5
1. 2. 3.	Gender, Female ; Male Age (years), Mean ± SD Length of symptom (month), Mean ±SD	4 ; 1 50,6 ± 2,97 12 ± 6,96

Shoulder pain is statistically significantly decreased for all the subjects. Mean pain NRS was decreased from 6 point at the baseline to 1 point after 4 weeks treatment. (Table 2)

Table 2: Numeric rating scale at initial and after 4 weeks intervention of Reswt.

Pain	NRS initial (Mean ± SD)	NRS 4 weeks (Mean ± SD)	p
NRS	6 ± 0.71	1.20 ± 0.44	0.000

Mean passive shoulder range of motions are statistically significantly increased in all planes after 4 weeks after radial rESWT (Table 3). Shoulder flexion range of motion was increased from 126 degrees at baseline to 156 degrees after the treatment. Shoulder abduction range of motion was increased from 76 degrees at baseline to 111 degrees after the treatment. Shoulder external rotation range of motion was increased from 23 degress at baseline to 48 degrees after the treatment. Shoulder internal rotation range of motion was increased from 43 degrees at baseline to 63 degrees after the treatment.

Table 3: Shoulder range of motion at initial and after 4 weeks intervention of rESWT.

Passive Shoulder ROM	ROM initial (Mean ± SD)	ROM 4 weeks (Mean ± SD)	p
Flexion	126 ± 21.91	156 ± 20.73	0.003
Abduction	76 ± 17.82	111 ± 27.48	0.011
Eksternal Rotation	23 ± 14.83	48 ± 11.51	0.001
Internal Rotation	43 ± 12.04	63 ± 13.04	0.003

Function that measured by the DASH questionnaire improved after 4 weeks after radial rESWT (Table 4). There was a statistically significant decreased in mean DASH scores from 53 at baseline to 16 after the treatment.

Table 4: Functional (DASH score) at initial and after 4 weeks intervention of rESWT.

Functional	DASH Score initial (Mean ± SD)	DASH Score 4 weeks (Mean ± SD)	p
DASH questionnaire	53 ± 10.64	16,98 ± 11.47	0.01

Three subjects were reported discomfort or pain when rESWT is applied at the first week of treatment, because of that the rESWT application was interrupted, but all of the patients were able to completed therapy. There are no adverse events that reported in this study.

4 DISCUSSIONS

In the present preliminary study, five patients with adhesive capsulitis assigned to receive rESWT treatment. This study has reported the successful positive change use of rESWT in treating patients

with shoulder adhesive capsulitis. Clinically and statistically significant differences were shown in pain, passive shoulder ROM and functional outcomes that measure in rESWT treated patients.

The characteristics of the all subjects in the present study consist of age, onset, symptoms, were truly representative of the reported shoulder adhesive capsulitis patient population.

The shock waves were delivered to two separate locations at posterior-to-anterior direction and anterior-to-posterior direction. In the present study, we did not deliver rESWT in a third oblique direction into the glenohumeral joint at about one finger breadth beyond the anterior border of the acromion tip (Chen et al. 2014) because the arthroscopic findings showed that adhesions occur more in the descendants fold and surrounding synovium (Vahdatpour et al. 2018). Therefore, stimulation from anterior and posterior directions is more effective than of the lateral direction (Vahdatpour et al. 2018).

The present study results in pain, passive shoulder ROM and functional outcomes are similar to those reported by Hussein et al., who performed a double-blind RCT to evaluate the effectiveness of rESWT that applied 2000 impulses each session, with an air pressure of 3.5 bars, an EFD of 0.16 mJ/mm^2 and a frequency of 8 Hz and proper session intervals. Adverse events that reported in those studies is hematomas, which lasted from 2 to 4 days, were that observed in 5.6% patients; no associated discomfort or pain was reported and the rESWT application was not interrupted (Hussein et al. 2015). This present study using rESWT with air pressure of 2.5 bar, with the same frequency and interval as the previous study, and EFD of 0.11 mJ/mm^2 that considered to be a low energy dose (Speed 2004), resulting significant changes in all outcome measures; no adverse events (hematomas, etc) as found in previous studies.

Studies that conducted rESWT in adhesive capsulitis patients using several intervals. Previous study that applied rESWT with an intervals 10 to 14 days show that low dose rESWT does not reduce pain or improve function in chronic rotator cuff tendinitis patient (Kolk et al. 2013). This present study show more effective responses rESWT with proper session intervals that similar with previous study that applied rESWT in adhesive capsulitis patient using 1 weeks intervals (Hussein et al. 2015) (Vahdatpour et al. 2018).

Shock wave therapy stimulates soft-tissue healing, increases blood flow to the treated site and induces an inflammatory-mediated healing process, and has been used in treating soft-tissue disorders (Chen et al. 2014). Shock wave therapy using fESWT was reported successful treating pathological shoulder conditions, previous use of in primary shoulder adhesive capsulitis and frozen shoulder, (Chen et al. 2014)(Vahdatpour et al. 2018) while the reported use of rESWT also successful treating frozen shoulder (Hussein et al. 2015).

The present study shows that effect of rESWT for hyperstimulation analgesia and neovascularization could be attributed to the pain relief (Yuan et al. 2018). Effect ESWT for anti-inflammatory, antifibrotic effects, tissue healing, and increased flexibility of the collagen fibers and tendons, could be attributed to increase of the range of motion (Vahdatpour et al. 2018). Consequent functional improvement of shoulder joint would result from the decrease in pain and the increase in mobility.

The present study has several limitations. This study had a small sample size and there is no control group. The follow up time was too short to determine the longterm effects of treatment. We suggest to do a further investigation with larger sample size, with short and long term evaluation for effect of low dose rESWT on adhesive capsulitis patient with comparison to conventional therapy.

5 CONCLUSIONS

The low energy rESWT resulted in significant clinical and statistical improvement pain, passive shoulder ROM and functional outcomes in patients with shoulder adhesive capsulitis. It could be considered low energy rESWT as an effective optimal treatment alternative in shoulder adhesive capsulitis, and safe without serious adverse event.

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