# Effects of Extracorporeal Shockwave Therapy in Long Term Functional Outcomes of Shoulder Adhesive Capsulitis

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### Abstract

Background: Adhesive capsulitis is typically marked with pain and a gradual and limitation in shoulder range of motion due which gravely affect the activities of daily living in patients. Extracorporeal Shockwave Therapy (ESWT) has been extensively used as an alternate to its surgical management but its long term effects on function are not still reported. Objective: To determine the Effects of Extracorporeal Shockwave Therapy in Long Term Functional Outcomes of Shoulder Adhesive Capsulitis. Methods: An interventional randomized controlled trial was conducted at Horizon Hospital Lahore, from July 2020 to December 2020. On the basis of inclusion criteria, 50 patients were included after obtained informed consent and randomly divided into two equal groups. Group A was given extracorporeal shockwave therapy along with conventional therapy while group B was only given conventional therapy. Both groups were assessed by using Constant Shoulder Scale (CSS) and Oxford Shoulder Score (OSS) at baseline, 4th, 8th, 12th and 24th week of treatment. The data was entered and analyzed using SPSS 21. Results: Findings revealed that differences between two groups were found to be statistically important, CSS score in ESWT group and conventional group were  $86.67 \pm 5.15 vs. 73.14 \pm 1.52$  points (p-value  $\leq 0.05$ ), respectively and OSS score was in both groups,  $54.24 \pm 1.14 vs. 38.95 \pm 1.40$  points (p-value  $\leq 0.05$ ), respectively at 24<sup>th</sup> week of follow-up. **Conclusion:** Extracorporeal shockwave therapy and conservative therapy both were effective in reducing pain and improving function in adhesive capsulitis patients.

**Keywords**: Adhesive capsulitis; Shockwave therapy; Oxford Shoulder Score (OSS); Constant Shoulder Scale (CSS)

# Introduction

Adhesive Capsulitis (AC) is one of the highest and commonly found problems of the upper extremities. [1] Cyriax explained the restriction pattern (capsular pattern) of shoulder joint capsule that tell us that external-rotation would be the 1st movement that will be restrained and after that there will be abduction of the joint followed by medial rotation. <sup>[2]</sup> Adhesive capsulitis is categorized as primary and secondary.<sup>[3]</sup> Primary adhesive capsulitis can be termed as "idiopathic"; having no proper cause and it is a self-restraining condition which gets normal within 2 years to 4 years, while several researchers proved that, patients face systematic restrictions, painfulness and weakness on long term follow-up.<sup>[4]</sup> But the other one that is secondary adhesive capsulitis is always caused because of some pathology. Ranging between capsular inflammation and fibrosis, it is categorized into four stages on terms of its arthroscopic and histological presence of the capsule of shoulder joint. These stages are "pre-adhesive, acute adhesive synovitis, maturation stage and chronic stage". [5]

Adhesive capsulitis affects 2% to 5% of the whole population and females of 40 years-60 years of age <sup>[6,7]</sup> are more prone to it as compared to males and the interesting thing is that the non-dominant hand of the patient involves first. <sup>[8]</sup> The chances of contra lateral shoulder involvement are increased by 5%-34% if the person already has other shoulder affected. It was reported that bilateral shoulder involvement is also seen in 14% of the cases. <sup>[9]</sup> In this condition, we have two options, "surgical management and non-surgical management". In a retrospective review of 2340 patients, about 89.5% of AC cases have been marked successful without any further notice of any surgical intervention. <sup>[10]</sup> A new treatment method is gaining attention now a day that is Extracorporeal Shockwave Therapy (ESWT). <sup>[11-13]</sup>

Extracorporeal shockwave therapy is characterized as a new procedure used for adhesive capsulitis in which the shockwaves generated through the instrument help improvises the circulation and activates the inflammatory mediated healing process. <sup>[2,14]</sup> Therapeutic extracorporeal shockwaves are of two classes, one is focused shockwaves, produced by using electro hydraulic, electromagnetic and piezoelectric methods. It has greater tissue

**How to cite this article:** Farhat MA, et al. Effects of Extracorporeal Shockwave Therapy in Long Term Functional Outcomes of Shoulder Adhesive Capsulitis. Ann Med Health Sci Res. 2021;11:67-70.

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penetration power (10 cm) and larger impact force and the on the other hand, is radial shockwaves produced by air compressor and are pneumatic waves and considered as an alternative for the focused shockwaves. <sup>[15]</sup> The rationale of this study was to compare the treatment effects and evaluate the longterm functional outcomes of ESWT and conventional therapy on pain, Range of Motion (ROM) and functional outcome in patients with shoulder adhesive capsulitis.

## **Materials and Methods**

#### **Design and settings**

An interventional randomized controlled trial (ClinicalTrials.gov Identifier: NCT04578366) was conducted at Horizon Hospital Lahore, from July 2020 to December 2020. Ethical approval was gained from Institutional Review Board (IRB) committee of Riphah International University Lahore campus. All research procedure in this study was conducted in accordance with the principals set forth in Declaration of Helsinki.

#### Sample selection and sample size

A total of 65 patients with adhesive capsulitis were selected on the volunteer basis from the free medical campus conducted at the same setting. Informed written consent was taken. The sample size was calculated by WHO sample size with following parameters; the mean disability index (DASH) score in control group 52.5 and in treatment group was 54.8, Confidence Interval (CI) 95%, and power of test was 80%. <sup>[4]</sup> Out of those 65 patients, 50 met the inclusion criteria and entered the trial with non-probability consecutive sampling technique.

Inclusion criteria included; patients between the age of 35 years-65 years with shoulder pain, having relapsed or episode of pain score  $\geq 5$  at assessment with a previous history of

pain from at least last 2 months, restriction of motion (>50% ROM loss in  $\geq$  2 directions in abduction, flexion and external rotation), no other treatment was taken except analgesics with unresponsive ROM restriction from the last 2 months, did not undergo steroidal injection or manipulation under anesthesia. Patients with bilateral shoulder involvement, history of previous surgery of the shoulder, shoulder fracture, cancer, glenohumeral or acromioclavicular arthritis, inflammatory disorders, bleeding disorders, any neuromuscular disorders, severe osteoporosis, pulmonary diseases, pregnancy, implanted pacemaker, and patients with Covid-19 positive (on PCR findings) were excluded from the study.

### Treatment protocol and data collection

The researcher conducted a thorough initial examination and assessment of shoulder region after which patients were allocated in experimental (A) and control (B) groups via computerized method. Randomization sequence was computergenerated numbers by a biostatistician and allocation was sealed in opaque envelopes to ensure concealment. The patient filled the "Constant Shoulder Score (CSS)" and "Oxford Shoulder Score (OSS)" as subjective measure. Controlled group was given conventional treatment that includes hot pack for 20 minutes, ultrasound for 10 min (3-MHz frequency) at 1.5 W/cm<sup>2</sup>, mobilizations, stretching, Codman exercises, and isometrics of shoulder. Experimental group was given "extracorporeal shockwave therapy" in poster-anterior, antero-posterior and oblique directions along with conventional therapy used for controlled group. ESWT given to experimental group was with 2000 impulses/treatment. The device's air pressure was equal to 3.5 bars, Energy Flux Density (EFD)  $\frac{1}{4} \times 0.16$  mJ/mm2, applicator was of 15 mm and the impulses were applied at a frequency of 8 Hz. 16 One session of ESWT and traditional

Age (years)		Group A (ESWT) n=25	Group B (Conventional) n=25	p-value	
		46.68 ± 7.85	47.80 ± 8.48	0.63	
Gender	Male	8 (32%)	9 (36%)	0.213	
	Female	17 (68%)	16 (64%)		
	Normal	10 (40%)	4 (16%)		
BMI	Overweight	8 (32%)	7 (28%)	0.113	
	Obese	7 (28%)	14 (56%)		
Affected Arm	Left	13 (52%)	9 (36%)	0.055	
	Right	12 (48%)	16 (64%)		
Symptoms duration	3 months-9 months	15 (60%)	17 (68%)	0.051	
	10 months-14 months	10 (40%)	8 (32%)		

Table 2: Comparison of constant shoulder score at pre-treatment, post-treatment and follow at 8, 12, 24th weeks. Level of Assessment Groups Mean ± SD t\* P-value 23.12 ± 1.24 Α Pre-treatment, 0 week 1.088 0.282 В 22.68 ± 1.60 А 43.83 ± 7.31 Post-treatment, 4th week 0.743 0.462 В 42.33 ± 6.67 A 56.78 ± 0.74 Follow-up at 8th week 0.001 1 В 56.78 ± 0.74 А 65.0 ± 3.35 Follow-up at 12th week 1.172 0.248 В 63.82 ± 3.37 А 86.67 ± 5.15 Follow-up at 24th week 11.799 0.0001 в 73.14 ± 1.52 \*: Independent sample t test

Annals of Medical and Health Sciences Research | Volume 11 | Issue S4 | September-October 2021

Level of Assessment	Groups	Numbers of pt.	Mean ± SD	t*	P-value
Pre-treatment. 0 week	А	25	16.48 ± 1.83	0.001	1
Pre-treatment, 0 week	В	25	16.48 ± 1.64		
Deat the streamt, 4th weak	А	24	34.75 ± 5.37	9.423	0.0001
Post-treatment, 4th week	В	24	23.79 ± 1.91		
	А	23	45.13 ± 2.62	26.133	0.0001
Follow-up at 8th week	В	23	29.78 ± 1.04		
Follow up at 19th weak	А	22	51.0 ± 0.76	48.651	0.0001
Follow-up at 12th week	В	23	33.96 ± 1.49		
Fallow we at 24th weak	А	21	54.24 ± 1.14	39.449	0.0001
Follow-up at 24th week	В	22	38.95 ± 1.40		

treatment on alternate days was given for four weeks. Data was collected at baseline (initial assessment), then at  $4^{th}$  week post treatment. The follow-up period was  $8^{th}$  week,  $12^{th}$  week and 24th week.

#### **Data analysis**

Data analysis was done with SPSS version 21. Normality of the data was assessed by Shapiro-Wilks test of normality and uniformity, based on which parametric or nonparametric test was applied to determine within the group and across the group difference in two groups. To determine any significant difference across the two groups we used independent samples t test. A p value  $\leq 0.05$  was considered as significant.

#### Results

The total number of patients was 50 with 25 in each group. Two patient in each group were dropped out due to sickness at post treatment period and at follow-up period (4<sup>th</sup> week and 8<sup>th</sup> week, n=46). One patient in group A was dropped out due to Covid-19 positive at follow-up period in 12<sup>th</sup> week (n=45). One patient in each was dropped out due to personal reason at follow-up period in 24<sup>th</sup> week (n=43). 21 patients in group A and 22 patients in group B were final analyzed at follow-up period in 24<sup>th</sup> week. The demographic characteristics of patients were studied [Table 1] and Shapiro Wilk test was used for normative data (p-value  $\geq 0.05$ ). Comparison of constant shoulder score and oxford shoulder score at the end of 24<sup>th</sup> week showed significant different across the two treatment groups [Tables 2 and 3].

## **Discussion**

This study was conducted to compare and find the effects of extracorporeal shockwave therapy and conservative therapy on long term pain and functional outcomes of patients with adhesive capsulitis. While analyzing the outcomes measures of this study, it was observed that significant improvement was found in both groups, but extracorporeal shockwave therapy showed improved results in terms of long term pain and functional outcome than conservative treatment. Our study was in agreement with the previous study done by Hussein et al. <sup>[4]</sup> in which they worked on the hypothesis that radial extracorporeal shockwave therapy is surely efficient and safe option in treating adhesive capsulitis. In comparison to placebo treatment, patients that were treated with radial ESWT showed marked statistically significantly reduction in VAS score by averaged 3.5 points and

prominently improvement in DASH score by 53.8 points, at all follow-up examinations. In our study we compared Constant Shoulder Score (CSS) and Oxford Shoulder Score (OSS) of extracorporeal shockwaves therapy with 86.7 points and 54.2 points, respectively at 24th week follow-up assessment. Pain and ROM scales are included in these two scales, CSS and OSS which we used to assessed the patients.

Chen et al. [16] conducted an RCT, they included 40 patients having primary adhesive capsulitis to compare whether ESWT show better improvement in functional outcome or oral steroid therapy. Functional outcomes evaluation was done using the tools Constant Shoulder Score (CSS) and Oxford Shoulder Score (OSS), both groups were having equal functional scores at baseline. After 4 weeks' treatment plan, the CSS in ESWT group was improved significantly in comparison with the steroid therapy (p=0.009). After 6 weeks, the EWST group showed marked improvement in both CSS and OSS as compared to steroid group (P<0.001 and P=0.020, respectively). At the end of 12 weeks, the final evaluation, the ESWT still showed marked improvement than the steroid group in terms of CSS and OSS evaluation (p=0.041 and p=0.045, respectively). Whereas, in our study CSS and OSS scores were significantly improved in ESWT group as compared to conventional group (p=0.0001, respectively) at 24th week follow-up assessment.

A study was done by Park et al. [14] to examine the effects of ESWT on patient pain and functions with diabetic frozen shoulder. They used two tools to measure the pain and degree of functional disorder and the tools were VAS and patient-specific functional scale. In comparison both groups showed significant improvement in VAS and patient-specific functional scale; however experimental group showed lower score as compared to the control group. But in our study intervention protocols, ESWT proved to be a good addition in treatment of adhesive capsulitis. Due to the Covid-19 lockdown that was imposed nationwide, no physiotherapist could be hired as thus the research administrator had to himself provide interventions. Also, there was no funding source to hire another physiotherapist. Patients dropped out due to Covid-19 during the study. Adhesive capsulitis treatment is itself a prolong treatment so patient might become loose interest in treatment due to prolong follow-up. Future researches should include a group of patients on who wait and see policy is administered in order to compare and see the actual clinical difference produced in response to ESWT.

## Conclusion

This study concluded that both extracorporeal shockwave therapy and conservative therapy were effective in reducing pain of adhesive capsulitis and improved constant shoulder score and oxford shoulder score. The results were statistically significant for both groups, though the extracorporeal shockwave therapy group found better than conservative only group in terms of mentioned outcome measures on the basis of mean differences.

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