



Original Article

Evaluating the Efficacy of High-energy Extracorporeal Shockwave Therapy Aimed at Treating Calcified Shoulder (ESWT-CS): a study protocol for a Randomized Controlled Trial

Arooj Fatima^{1*} and Shiza Kazmi²¹University Institute of Physical Therapy, University of Lahore, Lahore, Pakistan²University of Management & Technology* arooj.fatima1@uipt.uol.edu.pk

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***Corresponding Author:**

Arooj Fatima
University Institute of Physical Therapy, University of Lahore, Lahore, Pakistan
arooj.fatima1@uipt.uol.edu.pk

ABSTRACT

Shockwave therapy is a solid scientifically based medical tool used to manage calcified shoulder. This therapy, along with its pros and cons, is paving its way among armamentarium of interventions for musculoskeletal disorders. **Objective:** To determine efficacy of extracorporeal shockwave therapy on subjective and objective measures in patients with calcified shoulder. **Methods:** Single-blinded, parallel-group, randomized trial will be conducted on sample of 48 participants recruited through convenient sampling. Patients with calcified shoulder tendinopathy, aged between 30-55 years and both gender will be included. Outcome measures will be numeric pain rating scale, Constant and Murley score, Western Ontario rotator cuff index, shoulder ROM and radiological outcomes. Current study has been initiated in June 2020 till enrollment in December 2020. The quantitative data would present in the form of mean and standard deviation. After fulfilling the parametric assumptions, data will be analyzed using independent sample t-test/Mann Whitney test. Repeated measure ANOVA/Friedman test for pair-wise comparisons for follow-ups will be used to determine the effects of treatment within the groups at baseline, in 6th week and 12th week after commencement of treatment. **Conclusions:** Evidence reported related to shockwave therapy for tendinopathy shows less quality and less number of randomized trials done, with no comparable groups and methodological deficiencies of studies. **Trial registration:** Approval was obtained from Institutional Review Board Committee (ref: IRB-UOL-FAHS/693/2020). The study was registered on 28th March 2020 in Iranian Registry of Clinical trials (IRCT), its registration reference number is IRCT20200204046373N1 <https://irct.ir/trial/45657>.

INTRODUCTION

Rotator cuff (RC) tendinopathy presented as pain and weakness in shoulder, during shoulder external rotation and flexion [1]. Glenohumeral (GH) pain is third most prevalent musculoskeletal problem that affects quality of life and prevalence is about 10% [2]. Frequent cause of RC disorder is subacromial impingement syndrome (SIS) [3]. RC disease responsible for pain and functional disability has an effect on quality of life [4]. The cause of subacromial pain may range from its bursitis to chronic degenerative changes and full RC ruptures [5]. Calcified shoulder (CS) commonly affects supraspinatus tendon in middle-aged women. Injury or

fatigue to the RC muscles can cause reduced ability to keep humeral head depressed in glenoid cavity, causing impingement of subacromial bursa and RC tendons during arm movement [6]. This disorder is used to signify both pain and functional disability related to RC [7]. Prevalence of calcified deposits in shoulder is found to be 7.8% in asymptomatic patients and 42.5% in subjects with SIS. Calcified shoulder is characterized by deposits of hydroxyapatite crystals in RC tendons, frequently in supraspinatus tendon [8]. Multi-factorial etiology of rotator cuff tendinopathy has involved both extrinsic and intrinsic

mechanisms. Factors like carotid intima-media thickness or obesity are associated with the pain in shoulder. Diabetes mellitus (type-1) and obesity are considered to be associated with chronic shoulder tendinitis [9]. Conservative treatment is of prior option, along with corticosteroid injection or with different physiotherapy interventions [10]. Evidence has suggested certain treatments as effective [11]. However fewer studies have been done and they have methodological deficiencies [12]. Therefore well designed randomized trials are required. Arthroscopic subacromial decompression is recommended when conservative treatment failed to relieve symptoms [13]. Extracorporeal shockwave therapy (ESWT) is considered to be a non-invasive procedure that plays role in disintegration and dissolution of calcified deposits. Shockwaves are high pressure acoustic waves that also reduce enthesopathic pain and enhance functionality of limbs [14]. ESWT is considered effective for calcified and non-calcified tendinopathy that may reduce the need for surgical procedure [15]. It can be classified as high-energy, low and medium extracorporeal shockwaves [16]. Recent research on renal stones explained that because of the cavitation effects, the fragmentation efficiency is insignificantly enhancing data delay of between 400 and 250 ms between shockwaves. Evidence reported that cavitation have disintegrating effects on Ca deposits [17]. Shockwave therapy is a therapeutic tool used for the treatment of RC tendinopathy. Evidence reported shows less quality and less number of randomized trials done, with no comparable groups and methodological deficiencies of studies. For satisfactory and durable alleviation of symptoms, there is need for differential treatment which can contribute to improve patient's condition. Therefore, this parallel-group, randomized trial is designed to evaluate the effects of high-energy ESWT on outcome measures in patients having shoulder tendinopathy.

METHODS

A parallel-group, randomized controlled trial will be conducted at Lifeline Health Care and Pain Centre, Lahore. It has been started in August 2020 till last enrollment in December 2020. In this study, 30 participants will be estimated (15 in each group) having 95% confidence interval and 90% power of the study. However, 48 patients (24 per group) will be recruited after adding 20% dropout [22]. Convenient sampling would be used to recruit participants with calcified shoulder, aged between 30-55 years, both gender and having minimum three months history of shoulder pain, radiological evidence type A and B calcification (≥ 1 cm) [16] and Neer's test for impingement should be positive [23]. Patients having primary joint trauma or infection in shoulder region, any instability in shoulder, malignancies and nerve injuries, history of any fracture or

surgery around shoulder or having metallic implants will be excluded.

Participants who fulfilled selection criteria will be included, with similar baseline characteristics after taking informed consent. The assessor would be kept blind throughout the trial. The participants will be randomly assigned to any of two groups by using random number generator. Random allocation to all groups will be ensured, from all study personnel and participants by entry of data into computer randomization program immediately. Opaque envelopes will be used to conceal group assignments.

Intervention group: High-energy extra-corporeal shockwave therapy will be given to patients along with routine physical therapy treatment which comprises of:

- General exercise plan (free exercises, strengthening, and stretching exercises of shoulder abductors and flexors) performed alternately in a week [24].

Shockwave therapy: In this study, shockwave therapy defined as >0.28 mJ/mm² as high-ESWT is performed as: [16].

- 6 sessions for first 2 weeks (alternate days)
- 1 sessions/week for next 6 weeks
- Participants in group receiving high-energy shockwaves i.e., 2000 shockwaves of 0.32mJ/mm² per treatment. About 120 impulses were applied per minute. The whole session will take one hour.

Control group: To treat calcified tendinopathy, routine physical therapy will be given in this group.

The data will be collected at baseline, at 6th and 12th week after receiving therapy in both groups. Ultrasonography will be examined to check the size of Ca deposits pre- and post-treatment sessions.

Outcome measures:

- Numeric Pain Rating Scale
- Shoulder Range of Motion
- Constant and Murley Score
- Western Ontario Rotator Cuff Index
- Radiological outcomes

Data Analysis Procedure: Data would be analyzed and presented as mean and standard deviations. The percentages will be calculated and bar or pie charts would be drawn for qualitative data like gender. After fulfilling the parametric assumptions, independent sample t-test/Mann Whitney test will be calculated. Repeated measure ANOVA/Friedman test for pair-wise comparisons for follow ups will be used to determine the effects of treatment within the groups at baseline, in 6th week and 12th week after commencement of treatment.

Adverse effects: No major effects reported with this therapy. However, mild bruising or hematoma formation can occur.

Ethics and dissemination: Approval was gained from Institutional Review Board Committee (ref: IRB-UOL-FAHS/693/2020). The study was registered on 28th March 2020 in Iranian Registry of Clinical trials (IRCT); its registration reference number is IRCT20200204046373N1. Study findings will be submitted for publication in journal.

Statement of confidentiality: Individual participants' medical or personal information obtained is considered confidential, and disclosure is prohibited.

Research Question:
Will ESWT-CS treat calcified Shoulder?

Population:
Patients with calcified RC tendinopathy, either gender, aged between 30-55 years

Intervention
High-energy extracorporeal shockwave therapy aimed at treating calcified shoulder

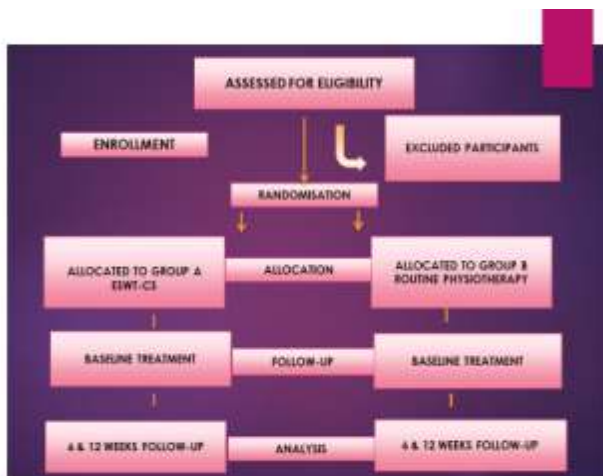
Comparison:
Participants with calcified shoulder and following routine physical therapy treatment

Outcome measures
Shoulder ROM
NPRS
WORC Index
Radiological outcomes
Constant and Murley score

Time: 12 weeks

- *RC: Rotator cuff
- *ROM: Range of motion
- *NPRS: Numeric Pain Rating Scale
- *WORC: Western Ontario Rotator Cuff Index

Figure 1: A randomized controlled trial evaluating the efficacy of extracorporeal shockwave therapy aimed at treating calcified shoulder(ESWT-CS)—PICOT format.



ESWT-CS: Extracorporeal shockwave therapy – Calcified shoulder

Figure 2: ESWT-CS Trial Design The flow chart summarizes the design of ESWT-CS trial aimed at treating calcified shoulder.

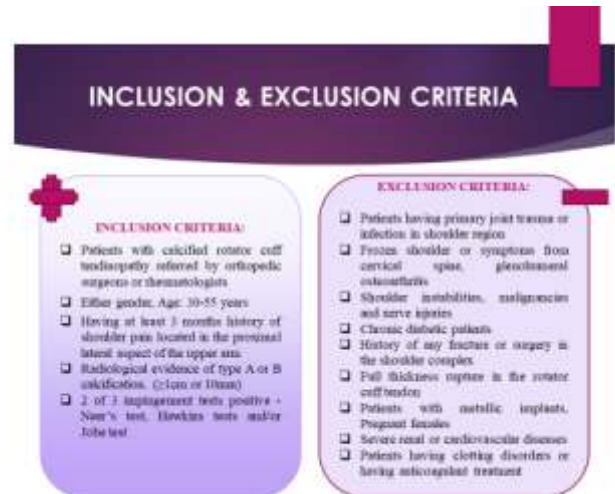


Figure 3: Inclusion and exclusion criteria for ESWT-CS trial aimed at treating calcified shoulder

DISCUSSION

Calcific tendinopathy is one of the most prevalent causes of shoulder pain. Recent trial demonstrates that middle-aged women with subacromial pain syndrome (SAPS) and a calcific deposit (>1.5 cm) are more prone to calcific shoulder [8]. A prospective trial was performed to compare effects of ESWT for RC tendinopathy, 40 patients recruited, getting 6000 impulses of shockwaves under local anesthesia and low-energy (ED 0.33 mJ/mm²). Pain score reduction and functional improvement in Constant and Murley score (CMS) was observed but there is no statistical significant difference found after 12 weeks and 1 year follow-up [18]. In a single blinded, randomized study (2007) on calcifying RC tendinitis, 2500 shock waves were given in dual sessions. About 80 participants included having history from last three months, size measuring 10 mm or more and were re-assessed and there was much increase in CMS score (t-test, p=0.026) in the high-energy group than in lower. Ca deposits resorbed in 15% subjects with high-energy ESWT and 5% in low-energy. Significantly results were obtained after 3 months follow-up, but in most cases calcification size remained unchanged [16]. A controlled trial protocol (2003) conducted showing ESWT effectiveness for the treatment

of chronic RC calcifying tendonitis. In this multi-centered double-blinded study 144 patients were recruited, their informed consents were gained and subjects were randomly allocated in 3 groups. Primary outcomes were CMS scores while secondary were pain intensity and radiographic outcomes at three, six, and twelve months. Significant results were found in both ESWT groups in mean CMS score in comparison with placebo treatment. High-energy therapy was found more effective than lower one, but threshold energy was not defined in that study [19]. Limitations of study were use of sedation, undefined amount of shock wave energy, high drop-out rates. A single-blinded randomized controlled trial, RCT (2002) compared high-ESWT to placebo (n = 40) for supraspinatus tendinosis, testing whether shockwaves comprising 3 x 2000 pulses with the positive energy flux density ED+ of 0.33 mJ/mm² is more effective than placebo. No significant differences were found between the groups on pain in rest or activity, the Constant score or subjective improvement score after 1-year. On the basis of findings of this RCT, ESWT showed no clinically positive effects on tendinitis [20]. A systematic review comprises of 11 trials included 9 studies having calcified shoulder and two with calcified and non-calcified tendinopathy both. High-quality controlled trials are needed with more sample mass, better randomization and blinding procedure and better outcome measures [21]. Rotator cuff tendinopathy is considered to be a highly prevalent medical condition and physical rehabilitation plays an important role in recovery of these patients. However access to rehabilitation and follow up is limited. Despite documented benefits, many patients find it difficult to assess which rehabilitation services are more beneficial. However a literature gap exists when focusing on the role of advance physiotherapy as an alternative to traditional treatment in persons who are suffering from rotator cuff disease. This trial is designed to find the effects of extracorporeal shockwave therapy on pain score, functional ability and radiological outcomes in participants having calcified tendinopathy of RC.

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