

## Role of extracorporeal shockwave therapy in patients with rotator cuff tendinopathy: synthetic analysis of last two decades

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### Abstract

**Objective:** To explore current evidence on the effectiveness of shockwave therapy in patients with rotator cuff tendinopathy.

**Method:** The meta-analysis study was conducted at University of Lahore from May 2019 to December 2019 and comprised search on Cochrane, Medline, Embase, Physiotherapy Evidence Databases and other sources as well as unpublished grey literature related to shockwave therapy in patients with rotator cuff tendinopathy published between 2000 and 2019. Methodological quality assessment was performed using Cochrane risk of bias tool and the included studies were critically appraised using the Physiotherapy Evidence Databases scale.

**Results:** Of the 11 studies shortlisted, data was not extractable from 2 (18%). Of the 9 (82%) studies analysed, 8 (89%) were randomised trials and 1 (11%) was randomised pilot study. Overall, 4 (44.4%) studies had high quality and 5 (55.6%) fell in the fair category.

**Conclusion:** There was no consensus found on the efficacy of extracorporeal shockwave therapy compared to traditional rehabilitation among patients with rotator cuff tendinopathy.

**Keywords:** Extracorporeal shockwave therapy, Rotator cuff tendinopathy, Systematic review, Calcific tendinitis. (JPMA 71: 1627; 2021) DOI: <https://doi.org/10.47391/JPMA.02-190>

### Introduction

Rotator cuff (RC) tendinopathy is characterised by shoulder pain and weakness that occurs most commonly during external rotation and elevation of shoulder.<sup>1</sup> Subacromial impingement syndrome (SIS) is considered the commonest cause of RC tendinopathy.<sup>2</sup> The pathology of subacromial pain may range from subacromial bursitis to chronic degradative changes with severe tearing of RC muscles. RC tendinopathy is a potential source of pain in shoulder with prevalence around 14% in the adult population.<sup>3</sup> The incidence of RC disease is 0.3-5.5% and its prevalence is 0.5-7.4% annually, and there is insufficient evidence that advanced age and factors like personal, occupational and psychological and social ones are associated with its incidence.<sup>4</sup>

Calcified tendinopathy is the most prevalent cause of pain in shoulder with an estimation of 14% in adult population and characterized by presence of calcified deposits in these tendons, having multi-factorial etiology, involved both extrinsic and intrinsic mechanisms.<sup>5</sup> Intrinsic factors responsible for RC tendon degeneration with overload include biological, mechanical, anatomical changes in characteristics. Extrinsic factors are mostly responsible for bursal-side compression of RC tendons that affect the

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subacromial space and involves anatomical acromion anomalies, postural disorders, scapulohumeral kinematics variations, deficient muscular performance, and reduced extensibility of pectoralis minor.<sup>6</sup> The supraspinatus tendon because of its location is the most vulnerable tendon in the subacromial space. In SIS, supraspinatus tendon degeneration has been shown through histological examinations similar to the variations found in Achilles and patellar tendinopathies.<sup>7</sup>

A number of risk factors for RC disease have been identified, such as tennis elbow, Achilles tendinitis, oral corticosteroids use and diabetes mellitus (DM).<sup>8</sup>

The main contributing mechanism in this case is excessive mechanical loading. An adequate load placed on the tendon is effective in stimulating healing and maintaining tendon's integrity and vice versa.<sup>9</sup>

Metabolic factors comprise obesity and carotid intima-media thickness (CIMT). According to a study, atherosclerosis and altered glucose metabolism may be the underlying cause. Physical overload, stress or mechanical injuries can also be the contributing mechanical factors. In males, major associated factors for shoulder pain could be smoking, being overweight and having metabolic syndrome (MS).<sup>10</sup> Some trials have proved the effectiveness of certain exercises, but the summarised evidence is uncertain because of the limited number of trials and methodological deficiencies.<sup>11</sup>

Many therapeutic treatments are available for the management of rotator cuff pathologies but extracorporeal shockwave therapy (ESWT) has evolved to be a safe and cost-effective treatment.<sup>12</sup>

Shockwave therapy is considered to be a curative, non-invasive procedure that helps in disintegration and dissolution of calcific deposits. Shockwaves are high-pressure acoustic waves that also reduce enthesopathic pain, and enhance functionality of limbs. Extracorporeal shockwave therapy (ESWT) for tendinopathy is considered an alternative option to surgery when conservative intervention fails.<sup>13</sup> ESWT is a cost-effective treatment in both calcified and non-calcified RC tendinopathy cases.<sup>14</sup> Complications and adverse events of therapy might be taken into consideration before treating such patients.<sup>15</sup> A study reported no such major side effects happened in treatment group showing effective and safe therapy using shockwaves in individuals with RC tendinopathy.<sup>16</sup> Recently, this treatment option because of its non-invasive, fast and safe nature, is considered valuable.<sup>17</sup>

However literature gap exists when considering the role of advance rehabilitation services as a practical alternative to traditional rehabilitation in patients having RC disease. The current systematic literature review was planned to explore the effectiveness of ESWT in RC tendinopathy patients.

## Materials and Methods

The meta-analysis study was conducted at University of Lahore from May 2019 to December 2019, and comprised search on Cochrane, Medline, Embase, Physiotherapy Evidence Database (PEDro) databases and other sources as well as unpublished grey literature related to ESWT in patients with RC tendinopathy published over the last two decades from 2000 to 2019. The thorough search included trial registers, clinical study reports, dissertations and theses, conference abstracts and proceedings. The digital library of the Higher Education Commission (HEC), Islamabad, Pakistan, was also used for the purpose. The search through Pubmed also involved contacting local and international experts in the field and contacting the authors concerned for their opinions. The search strategy was designed by combining Boolean operators and key terms related to the study objectives, including 'rotator cuff tendinopathy', 'extracorporeal shockwave therapy', 'systematic review' and 'calcific tendinitis'. Hand searching of the references provided in the included studies was done to locate any relevant clinical trial missed through database search. Direct contact was made with local experts to locate any trial not spotted during the search. Two authors independently searched the databases and noted down all the relevant record.

The search, done using the population, intervention, control, and outcomes (PICOs)<sup>18</sup> format, encompassed human studies published in the English language. Full text articles were retrieved for eligibility, and in case of difference of opinion between the two researchers, it was resolved with a formal discussion followed by consultation with the supervisor and the co-supervisor, if needed.

The studies included were randomised controlled trials (RCTs) or pilot studies on the subject having outcome measures as visual analogue scale (VAS) and Constant-Murley score<sup>19</sup> (CMS), primary quantitative, or mixed-method research published in peer-reviewed journals, professional or scientific journals and articles published in the English language over the past two decades.

The studies excluded were the ones involving the presence of health-related medical conditions that could interfere with tests or the rehabilitation programme, or the one with only abstracts available, having copyrights issues, or published in non-English journals.

The 10-point PEDro scale<sup>20</sup> was used to assess the methodological quality of the studies. The scale has been used for the determination of both randomised as well as non-randomised health trials. A score of 7 or more was taken as good, while 5-6 was considered fair, and 4 or less indicated poor quality.

Data was synthesised through vote counting as a descriptive tool. Cochrane risk of bias (ROB) tool<sup>21</sup> was used for the assessment of the included studies. Pooled effect of means was estimated for outcomes of interest, such as pain, functional activities and radiological outcomes.

## Results

Of the 265 search results, 250(94.3%) related to PubMed, PEDro, and Cochrane Central Register of Controlled Trials(CENTRAL) databases, while 15(5.7%) were identified through other sources, like the clinical trial registry, Open Assess, thesis dissertations and journals. Of them, 25(9.4%) articles had their full text reviewed, and 11(44%) met the inclusion criteria. However data was not extractable from 2(18%) studies. Of the 9(82%) studies finally reviewed, 8(89%) were RCTs and 1(11%) was a prospective pilot study (Figure).

Each study was analysed on the basis of selection bias, performance bias and others. The characteristics of the included trials in terms of participants, type of intervention regimes, comparator group and outcomes were noted separately (Table1).

On the PEDro scale, 4(44.4%) studies were of high quality

**Table 1:** Characteristics of the included studies.

Study	Study Design	Sample size & Population	Intervention given	Follow-up duration	Outcomes	Results		p-value
						Group I	Group C	
Efe, Turgay (2014) <sup>27</sup>	Randomized Placebo Controlled trial	40 Non-calcific supraspinatus tendinopathy Age 52 (range 29-66 years) 20 Males 20 females	I: ESWT C: Sham ESWT	10 years	Pain at rest (VAS)	Pre* = -- LF* = 2.2 ± 2.3	Pre* = -- LF* = 2.3 ± 2.7	0.04 0.92 (ANCOVA)
					Functional activity (CMS)	Pre* = -- LF* = 105 ± 24	Pre* = -- LF* = 99 ± 31	0.02 0.49 (ANCOVA)
Loppolo F (2012) <sup>28</sup>	Single blind randomized clinical trial	68 Supraspinatus calcific tendinitis 68 patients, 28 Males, 40 females	I: High-energy ESWT C: Low-energy ESWT (4 sessions once a week)	12 months	Pain at rest (VAS)	Pre* = 8.45 ± 0.67 LF* = --	Pre* = 8.36 ± 0.78 LF* = --	<0.001
					Functional activity (CMS)	Pre* = 49.26 ± 8.56 LF* = --	Pre* = 47.70 ± 12.23 LF* = --	<0.001
Farr S (2011) <sup>29</sup>	Prospective pilot study	30 Calcific tendinitis 30 patients, 16 Males, 14 females	I: High-energy ESWT C: Low-energy ESWT (2 sessions once a week)	12 weeks	Pain at rest (VAS)	Pre* = 3.2 ± 1.7 LF* = 3.0 ± 3.5	Pre* = 4.4 ± 2.5 LF* = 3.3 ± 3.0	0.03
					Functional activity (CMS)	Pre* = 67.7 ± 14.7 LF* = 79.9 ± 19.3	Pre* = 60.2 ± 15.6 LF* = 80.3 ± 18.5	0.0001
Schofer MD (2009) <sup>30</sup>	A prospective randomised Controlled study	40 Chronic RC tendinopathy 20 in each group	I: High-energy ESWT C: Low-energy ESWT (3 sessions with 1 week interval)	1 year	Pain at rest (VAS)	Pre* = 5.65 ± 2.52 LF* = 2.11 ± 2.71	Pre* = 3.45 ± 2.44 LF* = 2.00 ± 2.25	0.237
					Functional activity (CMS)	Pre* = 46.37 ± 22.47 LF* = 88.45 ± 31.97	Pre* = 49.06 ± 20.52 LF* = 75.45 ± 33.87	0.899
Hsu CJ (2008) <sup>31</sup>	A prospective Randomised trial	46 Calcific tendinitis of shoulder	I: ESWT C: Sham ESWT (2 sessions with 2 weeks interval each)	1 year	Pain at rest (VAS)	Pre* = 7.2 LF* = 1.3	Pre* = 7.2 LF* = 6.8	<0.001
					Functional activity (CMS)	Pre* = 57.3 LF* = 88	Pre* = 56.2 LF* = 56.8	<0.001
Albert J-D (2007) <sup>32</sup>	A Randomised trial	80 Calcific tendinitis of RC (40 in each group) Age 18-75 years	I: High-energy ESWT C: Low-energy ESWT (Follow-up At baseline & 3 months post-treatment)	3 months	Pain at rest (VAS)	Pre* = 6.5 (0.0-9.8) LF* = 5.8(0.0- 8.2)	Pre* = 4.4(0.2- 9.0) LF* = 4.3(0.4-8.5)	<0.00001 0.061
					Functional activity (CMS)	Pre* = 50.7 (33.2 to 70.2) LF* = 63.2 (23.8 to 90.0)	Pre* = 50.3 (28.2 to 83.8) LF* = 54.8 (19.9 to 86.8)	<0.00001 0.026
Pleiner J (2004) <sup>33</sup>	Randomized controlled trial (double-blinded study)	43 (57 shoulders) with calcific tendinitis of shoulder 31 in treatment 26 in control group	I: High-energy ESWT C: Low-energy ESWT (2 sessions with 2 weeks interval each, Follow-up at 1 week, 3 & 7 months)	7 months	Pain at rest (VAS)	Pre* = 4.8 ± 2.6 LF* = 2.4 ± 2.2	Pre* = 4.3 ± 2.9 LF* = 3.8 ± 3.1	<0.001
					Functional activity (CMS)	Pre* = 46 ± 21 LF* = 106 ± 32	Pre* = 52 ± 22 LF* = 35 ± 9	<0.05

**Table 1:** Characteristics of the included studies. (Continued from previous page)

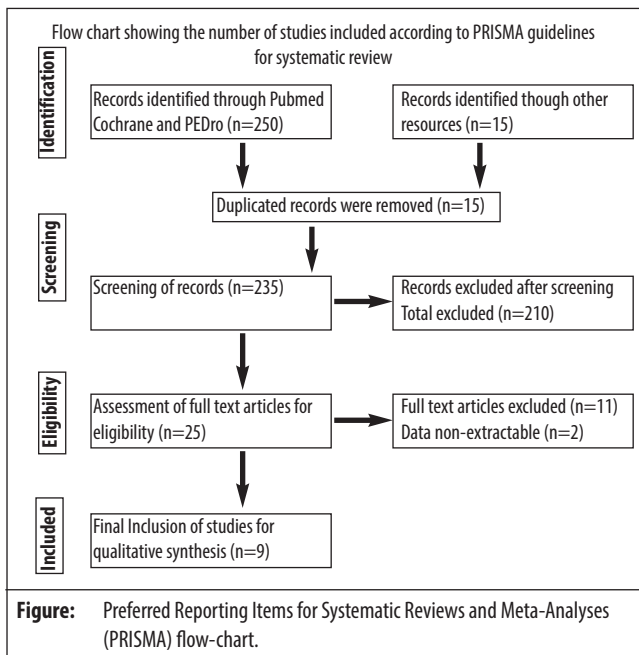
Study	Study Design	Sample size & Population	Intervention given	Follow-up duration	Outcomes	Results		p-value
						Group I	Group C	
Gerdesmeyer L (2003) <sup>34</sup>	A Randomised-controlled trial (double-blinded placebo controlled study)	144 Chronic calcific tendinitis of shoulder Aged 18 years or more	I: High-energy ESWT C: Sham ESWT (2 sessions with 2 weeks interval each)	12 months	Pain (VAS)	Pre* = 6.5 ± 1.3 LF* = -5.6 (-6.3 to 4.9)	Pre* = 5.6 ± 1.6 LF* = -1.9 (-2.7 to 1.2)	<0.001
					Functional activity (CMS)	Pre* = 60 ± 11 LF* = 31.6 (27.3-36.0)	Pre* = 64.2 ± 12.8 LF* = 13.7 (8.4-19.0)	<0.001
Schmitt J (2001) <sup>35</sup>	A prospective randomised trial	40 Non-calcific supraspinatus tendinopathy Age 52 (range 29-66 years) 20 Males 20 females	I: Low-energy ESWT C: Sham ESWT Follow-up at 6th & 12th week	12 weeks	Pain at rest (VAS)	Pre* = 5.35 ± 2.54 LF* = 2.30 ± 3.03	Pre* = 5.4 ± 3.0 LF* = 3.22 ± 2.82	>0.05
					Functional activity (CMS)	Pre* = 40.7 ± 13.29 LF* = 66.5 ± 37.92	Pre* = 42.2 ± 13.04 LF* = 64.39 ± 32.68	>0.05

VAS: Visual analogue scale; CMS: Constant Murley score; Pre\*: Pre-treatment; LF\*: Last follow-up; ESWT: Extra-corporeal shockwave therapy; p ≤ 0.05 was considered significant.

**Table-2:** Physiotherapy Evidence Database (PEDro) scoring of the included studies.

Study	2	3	4	5	6	7	8	9	10	11	Total Score	Quality
EfeTurgay <sup>27</sup>	Y	N	N	Y	N	N	Y	Y	Y	Y	6	Fair
Loppolo F <sup>28</sup>	Y	N	Y	Y	N	N	N	Y	Y	Y	6	Fair
Farr S <sup>29</sup>	Y	N	Y	Y	N	N	Y	N	Y	Y	6	Fair
Schofer MD <sup>30</sup>	Y	N	N	Y	N	Y	Y	N	Y	Y	6	Fair
Hsu CJ <sup>31</sup>	Y	N	N	Y	N	Y	Y	N	Y	Y	6	Fair
Albert J-D <sup>32</sup>	Y	N	Y	Y	N	Y	Y	Y	Y	Y	8	High
Pleiner J <sup>33</sup>	Y	N	Y	Y	N	Y	Y	N	Y	Y	7	High
Gerdesmeyer L <sup>34</sup>	Y	N	Y	Y	N	Y	Y	Y	Y	Y	8	High
Schmitt J <sup>35</sup>	Y	Y	N	Y	N	N	Y	Y	Y	Y	7	High
Percentage of Yes	100%	10%	50%	100%	0%	5%	90%	5%	100%	90%		

Y = Criteria satisfied; N = Criteria not satisfied



and 5(55.6%) were of fair category (Table 2).

**Discussion**

The most dynamic cause of shoulder pain is calcific tendinopathy which is characterised by deposition of calcium (Ca) oxalate crystals in RC tendons. Females aged 30-60 years with subacromial pain syndrome (SAPS) are more prone to calcified tendinopathy. Prevalence rate in asymptomatic patients is 7.8% and it is 42.5% in patients with SAPS.<sup>22</sup>

The current review found that most studies favoured ESWT as a practical alternative to surgical intervention for calcified deposits.

An RCT compared the effects of high-energy shockwave to placebo in patients with supraspinatus tendinopathy. Between the groups no significant difference was found on pain and CMS level after one year, concluding that the therapy appeared to have no effect on supraspinatus tendinopathy.<sup>23</sup>

A systematic review consisting of 11 non-randomised trials reported moderate evidence that high-energy shockwave therapy was effective in curing chronic RC tendinopathy. It concluded that high-quality RCTs were required with large sample size, better methodology and detailed outcome measures.<sup>24</sup>

The rehabilitation programme for patients with tendinopathy creates an immense challenge for practitioners and rehabilitation specialists. Most of the studies in the current systematic review concluded that shockwave therapy was a practical alternative to surgical intervention for calcified deposits.

Another study reported shockwave therapy as effective intervention in athletes and non-athletes, to treat refractory tendinitis.<sup>25</sup>

In a prospective RCT, subjects having RC tendinopathy when treated electromagnetic transduction therapy in addition to shockwaves showed improvement in pain intensity and functional outcomes in comparison to sham group.<sup>26</sup>

The current review revealed that although heterogeneity existed in the studies in aspects of study designs, locations, outcome measures and mode of delivery, there was a constant pattern encouraging the use of ESWT. A key point provided by the current systematic review is that evidence has been summarised regarding the utilisation of ESWT for improving pain and enhancing functional activity of patients having RC tendinopathy. The review opened a window of opportunity for practicing physical therapists in Pakistan to manage access and cost issues by applying ESWT as a practical alternative to surgery in cases of calcific deposits in RC muscles.

One of the important limitations of the current review is the level of quality of the included studies. Besides, different designs of study and the inclusion of only English-language studies limited the comparison element across literature. Finally, assessment of only three outcomes was considered. Future research is warranted to evaluate the utilisation of ESWT in real circumstances, using high-quality research methodologies.

## Conclusion

ESWT showed significant improvement in terms of reducing pain and improving functional mobility compared to traditional rehabilitation in patients with RC tendinopathy in some studies, but others found the difference to be non-significant. There is no consensus between the two interventions, but ESWT is an acceptable practical alternative among patients with RC tendinopathy.

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