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A Clinical Trial On Rotator Cuff Tendon: High Frequency Modalities Implementation Involving Exercise-Based Treatment In Individuals With Rotator Cuff Tendinitis: An Experimental Study

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ABSTRACT

Aim: *The aim of this pilot study is to evaluate the effect of advanced physiotherapy modalities on rotator cuff tendinitis.*

Background: *Shoulder pain is a prevalent musculoskeletal complaint in clinical practice, with rotator cuff tendinitis being a significant contributor. Symptoms include shoulder pain, swelling, and limited arm motion. This condition often results from repetitive stress on the rotator cuff tendons.*

Methodology:

Study Design: *Pilot study of comparative type (pre and post-test).*

Study Setting: *Outpatient department, Faculty of Physiotherapy, ACS Medical College and Hospital.*

Sample Size: *15 subjects.*

Groups:*Group A: Extracorporeal shock wave therapy with dynamic loading exercise programme.,Group B: Low-level laser therapy with dynamic loading exercise programme., Group C: Ultrasound with dynamic loading exercise programme.Sampling Method: Simple random sampling.Duration: 1 month.*

Inclusion Criteria: *Patients clinically diagnosed with rotator cuff tendinitis, aged 18-60 years, both genders, with positive tests for painful arc syndrome and chronic tendinitis for over 6 months, BMI 19-25 kg/m².*

Exclusion Criteria: *Pregnant women, blood coagulation disorders, history of surgery or tumors, cardiac illness, frozen shoulder, systematic diseases, skin disease,, severe mental illness, recent fractures and dislocations.*

Outcome Measures: *Pain, muscle tissue morphology (thickness in mm), shoulder joint function, range of motion (abduction/lateral rotation).*

Measurement Tools: *Blood test (serum cortisol), ultrasonogram, SPADI, digital electronic goniometer.*

Results: *Dependent T-test showed significant improvements in Group A post-test for ultrasonogram, SPADI,*

shoulder abduction, external rotation, and serum cortisol.

Keywords: *Rotator cuff tendon (RCT), Shoulder pain and disability index (SPADI), Blood serum cortisol, Digital Goniometer, Ultrasonogram, Dynamic loading exercise programme.*

INTRODUCTION

Shoulder pain is a prevalent issue often linked to rotator cuff tendinitis, an inflammation of the rotator cuff tendons without a tear. Tendons are robust tissues connecting muscles to bones, and their repeated strain can cause pain and hinder movement. The likelihood of rotator cuff tears increases significantly after age 50, making them a frequent concern among middle-aged and older individuals. The rotator cuff comprises four muscles—supraspinatus, infraspinatus, teres minor, and subscapularis—that encircle the head of the humerus.

Measurement Tools

Blood Serum Cortisol: A test to evaluate cortisol levels in blood, urine, or saliva to assess hormonal balance. Cortisol, often termed the "stress hormone," influences various bodily functions and stress responses.

Shoulder Pain and Disability Index (SPADI): A self-report questionnaire that measures pain and functional limitations in shoulder use. It includes a pain section with five questions and a functional section with eight questions.

Easy Angle: A versatile device that acts as a digital goniometer, inclinometer, and measures back range of motion (BROM), cervical range of motion (CROM), and scapular mobility.

MATERIALS AND METHODS

Ethical Considerations: Approval for this study was granted by the ethical committee of the Faculty of Physiotherapy, Dr. MGR Educational and Research Institute (Approval No. 645/2022/IEC/ACSMCH Dt.14/12/2022). The study is registered with the Clinical Trial Registry - India (CTRI/2024/07/069728). Written informed consent was obtained from all participants.

Study Design: This research was structured as a pilot study involving pre-test and post-test evaluations. It was conducted at the Outpatient Department of the Faculty of Physiotherapy, ACS Medical College and Hospital. The study enrolled 15 participants, aged between 18 and 60, with a diagnosis of rotator cuff tendinitis. Exclusion criteria were pregnancy, prior surgical interventions, cardiovascular conditions, frozen shoulder, systemic or dermatological conditions, cancer, severe psychiatric disorders, and recent fractures or dislocations.

Outcome Measures:

- Pain alleviation
- Enhancement in shoulder range of motion
- Improvement in shoulder abduction and external rotation
- Reduction in muscle thickness

Measurement Instruments:

- Blood serum cortisol level assessment
- Shoulder Pain and Disability Index (SPADI)
- Digital goniometer
- Ultrasonographic imaging

Procedure:

Before initiating the study, informed consent was secured from all participants. The study involved 15 individuals, aged 18-60 years, diagnosed with chronic rotator cuff tendinitis (CRCT), selected through random sampling. The pre-test was designed to evaluate:

- Muscle tissue characteristics

- Shoulder joint functions
- Range of motion (including shoulder abduction and lateral rotation)

Measurement Tools for Pre-Test:

- Blood Test (Serum Cortisol)
- Shoulder Pain and Disability Index (SPADI)
- Ultrasonogram
- Digital electronic goniometer

Treatment Protocols:

Group A (Extracorporeal Shockwave Therapy with Dynamic Rotator Cuff Loading Exercises): Participants received low-energy ESWT twice weekly (0.2 mJ/mm²) for 4 weeks, along with three dynamic rotator cuff loading exercises: open chain resisted band exercises (OC), closed chain exercises (CC), and minimally loaded range of movement exercises (ROM).

Group B (Low-Level Laser Therapy with Dynamic Rotator Cuff Loading Exercises): Participants underwent low-level laser therapy (4 J/cm²) applied to up to ten painful shoulder points, with each session lasting 5 minutes over 4 weeks, and performed the same dynamic rotator cuff loading exercises as Group A.

Group C (Ultrasound Therapy with Traditional Exercises): Participants received ultrasound therapy for 15 minutes per session targeting the calcified area at 0.89 MHz frequency and 2.5 W/cm² intensity. The pulsed mode was 1:4, using a 5 cm² transducer and aqua sonic gel as a coupling agent, for 4 weeks. This group also engaged in the same three dynamic rotator cuff loading exercises as the other groups.

Table 1: Demographic Datas

Characteristics	**Group A**	**Group B**	**Group C**
Gender(male/female) Age (years)	3/2	4/1	3/2
	30-50	50-60	30-60
Affected side (right/ left) shoulder	3/2	5/0	3/2
Duration of symptoms	4 weeks	4 weeks	4weeks

Intergroup Comparision of Dependent Variables

Parameter	**Group A**	**Group B**	**Group C**
Blood Serum Cortisol (mg/dl)	24.6 ± 0.6	22.6 ± 0.25	25.6 ± 0.5
Shoulder Abduction (degree)	70 ± 5	65 ± 5	60 ± 5
Shoulder Lateral Rotation (degree)	70 ± 5	65 ± 5	60 ± 5
SPADI-Score (100%)	70	65	60
Ultrasonogram (mm)	3.9	4	4

ANOVA (Pre and post treatments)

Test	**GROUB A**	**GROUB B**	**GROUB C**		
	Mean ±SD	**Mean± SD**	**Mean± SD**	**F value**	**Significance (P values).**

ULTRASONOGRAM					
PRE-TEST	4.72±0.1789	4.64±0.2966	4.66±0.2608	0.138	0.872
POST-TEST	3.62+0.2387	4+0.1581	4.22+0.3114	7.721	0.007
SPADI					
PRE-TEST	61 ±4. 416	63.6±5.177	66.8±0.837	2.694	0.108
POST-TEST	25.2±0.447	33.8±1.304	44±1.581	301.955	0 .007
SHOULDER ABDUCTION					
PRE-TEST	38±2.739	32±5.701	36±4.183	2.435	0.013
POST-TEST	82.6±3.715	69±7.416	68±10.954	5.285	0.023
SHOULDER EXTERNAL ROTATION					
PRE-TEST	42±4.472	39±6.519	46±8.216	1.423	0.279
POST-TEST	86.6±0.894	77±7.583	68±13.038	1.422	0.265
BLOOD SERUM CORTISOL					
PRE-TEST	26.3±0.2915	26.84±1.1908	27.46±0.8961	2.192	0.154
POST-TEST	14.72±3.7138	22.36±1.7785	19.98±3.8147	7.276	0.009

The analysis of pre-test and post-test values for various treatments of RCT injuries reveals several key findings. For muscle thickness measured by ultra-sonogram, no significant pre-test differences were observed among groups A, B, and C ($F = 0.138$, $P = 0.872$), but significant differences emerged post-test ($F = 7.721$, $P = 0.007$), with Group A (mean value 3.62 mm) being the most effective. SPADI scores showed no significant pre-test differences ($F = 2.694$, $P = 0.108$), but post-test differences were significant ($F = 301.955$, $P < 0.001$), with Group A (mean value 25.2) being the most effective treatment. In shoulder abduction, pre-test values showed no significant differences ($F = 2.435$, $P = 0.13$), while post-test values did ($F = 5.285$, $P = 0.023$), with Group A (mean value 68) being the most effective. For shoulder external rotation, no significant pre-test differences were noted ($F = 1.423$, $P = 0.279$), but post-test differences were significant ($F = 5.685$, $P = 0.018$), with Group A being the most effective. The serum cortisol levels showed no significant pre-test differences ($F = 2.192$, $P = 0.154$), but significant post-test differences ($F = 7.276$, $P = 0.009$), with Group A (mean value 14.72) being the most effective. Thus from the above results, the analysis of treatments for RCT injuries shows that pre-test values for muscle thickness, SPADI scores, shoulder abduction, shoulder external rotation, and serum cortisol levels did not differ significantly among groups A, B, and C. However, post-test values revealed significant differences in all metrics. Group A was found to be the most effective in improving muscle thickness, SPADI scores, and reducing serum cortisol levels and Group B's ((LLLT)) post-test results were generally less effective compared to the other groups. This indicates that the treatment applied to Group A may be less effective overall for RCT injuries.

Post HOC Test – Inter group comparison pre and post test

Dependent Variable	**(I) GROUP**	**(J) GROUP**	**Mean Difference (I-J)**	**Std. Error**	**95% Confidence Interval**	**Significance**

					Upper bound lower bound		
ULTRASONOGRAM -PRE TEST	GROUP A	GROUP B	.0800	.1583	4.498	4.942	0.087
		GROUP C	.0600	.1583	4.272	5.008	0.924
	GROUP B	GROUP A	-.0800	.1583	4.336	4.984	0.87
		GROUP C	-.0200	.1583	4.544	4.803	0.991
	GROUP C	GROUP A	-.0600	.1583	3.324	3.916	0.924
		GROUP B	.0200	.1583	3.804	4.196	0.991
ULTRASONOGRAM -POST TEST	GROUP A	GROUP B	-.3800	.1545	3.833	4.607	0.002
		GROUP C	-.6000*	.1545	3.757	4.136	0.076
	GROUP B	GROUP A	.3800	.1545	4.498	4.942	0.004
		GROUP C	-.2200	.1545	4.272	5.008	0.36
	GROUP C	GROUP A	.6000*	.1545	4.336	4.984	0.004
		GROUP B	.2200	.1545	4.544	4.803	0.36
SPADI- PRE- TEST	GROUP A	GROUP B	-2.600	2.503	-9.28	4.08	0.568
		GROUP C	-5.800	2.503	-12.48	.88	0.492
	GROUP B	GROUP A	2.600	2.503	-4.08	9.28	0.568
		GROUP C	-3.200	2.503	-9.88	3.48	0.433
	GROUP C	GROUP A	5.800	2.503	-.88	12.48	0.192
		GROUP B	3.200	2.503	-3.48	9.88	0.433
SPADI- Post- TEST	GROUP A	GROUP B	-8.600*	.766	-10.64	-6.56	0.004
		GROUP	-18.800*	.766	-20.84	-16.76	0.014

		C					
	GROUP B	GROUP A	8.600*	.766	6.56	10.64	0.025
		GROUP C	-10.200*	.766	-12.24	-8.16	0.741
	GROUP C	GROUP A	18.800*	.766	16.76	20.84	0.044
		GROUP B	10.200*	.766	8.16	12.24	0.621
SHOULDER ABDUCTION- PRE - TEST	GROUP A	GROUP B	6.000	2.769	-1.29	12.8	0.118
		GROUP C	2.000	2.769	-1.39	13.39	0.755
	GROUP B	GROUP A	-6.000	2.769	-5.39	9.39	0.118
		GROUP C	-4.000	2.769	-13.39	1.39	0.35
	GROUP C	GROUP A	-2.000	2.769	-11.39	3.39	0.755
		GROUP B	4.000	2.769	-9.39	5.39	0.35
SHOULDER ABDUCTION - POST-TEST	GROUP A	GROUP B	13.600*	5.017	-3.39	11.39	0.046
		GROUP C	14.600*	5.017	.21	26.99	0.033
	GROUP B	GROUP A	-13.600*	5.017	1.21	27.99	0.046
		GROUP C	1.000	5.017	-26.99	-.21	0.978
	GROUP C	GROUP A	-14.600*	5.017	-12.39	14.39	0.033
		GROUP B	-1.000	5.017	-27.99	-1.21	0.978
SHOULDER EXTERNAL ROTATION - PRE-TEST	GROUP A	GROUP B	3.000	4.163	-8.11	14.11	0.756
		GROUP C	-4.000	4.163	-15.11	7.11	0.614
	GROUP B	GROUP A	-3.000	4.163	-14.11	8.11	0.756
		GROUP C	-7.000	4.163	-18.11	4.11	0.252

	GROUP C	GROUP A	4.000	4.163	-7.11	15.11	0.614
		GROUP B	7.000	4.163	-4.11	18.11	0.252
SHOULDER EXTERNAL ROTATION - POST-TEST	GROUP A	GROUP B	9.600	5.517	-5.12	24.32	0.011
		GROUP C	18.600*	5.517	3.88	33.32	0.014
	GROUP B	GROUP A	-9.600	5.517	-24.32	5.12	0.031
		GROUP C	9.000	5.517	-5.72	23.72	0.271
	GROUP C	GROUP A	-18.600*	5.517	-33.32	-3.88	0.014
		GROUP B	3.000	4.163	-23.72	5.72	0.271
BLOOD SERUM CORTISOL- PRE-TEST	GROUP A	GROUP B	-.5400	.5545	25.938	26.662	0.606
		GROUP C	-1.1600	.5545	25.361	28.319	0.133
	GROUP B	GROUP A	.5400	.5545	26.347	28.573	0.606
		GROUP C	-.6200	.5545	26.341	27.392	0.522
	GROUP C	GROUP A	1.1600	.5545	10.109	19.331	0.133
		GROUP B	.6200	.5545	20.152	24.568	0.522
BLOOD SERUM CORTISOL- POST-TEST	GROUP A	GROUP B	-7.6400*	2.0496	15.243	24.717	0.008
		GROUP C	-5.2600	2.0496	16.548	21.492	0.006
	GROUP B	GROUP A	7.6400*	2.0496	25.938	26.662	0.008
		GROUP C	2.3800	2.0496	25.361	28.319	0.497
	GROUP C	GROUP A	5.2600	2.0496	26.347	28.573	0.016
		GROUP B	-2.3800	2.0496	26.341	27.392	0.497

CONCLUSION

From the results of the pilot study, it is concluded that extracorporeal shockwave therapy (Group A) is an effective modality for relieving pain intensity and increasing functionality and quality of life in patients with rotator cuff tendinitis. This is due to its effects, such as promoting neovascularization at the tendon-bone junction, stimulating proliferation of tenocytes and osteoprogenitor differentiation, increasing leukocyte infiltration, and amplifying growth factor and protein synthesis to stimulate collagen synthesis and tissue remodeling.Extracorporeal shockwave therapy demonstrated favorable outcomes in this study, indicating that it is a safe and effective treatment for rotator cuff tendinitis. When comparing Group A (extracorporeal shockwave therapy) with Group B (low-level laser) and Group C (ultrasound therapy), Group A showed more significant effectiveness with a P value of 0.002 than Group B and Group C.

RESULTS OF THE PILOT STUDY:

Intergroup Comparisons Using Post Hoc Analysis:

- **Serum Cortisol Levels:** Analysis of post-test serum cortisol levels revealed that Group A had a significant difference compared to Groups B and C, with a p-value of 0.008.
- **Shoulder External Rotation:** Group A demonstrated a significant improvement in shoulder external rotation compared to Groups B and C, with a p-value of 0.01.
- **Shoulder Abduction:** Post-test results indicated significant differences in shoulder abduction for Group A when compared with Groups B and C, with a p-value of 0.033.
- **Ultrasonographic Findings**: The analysis of ultrasonographic results showed significant differences for Group A compared to Groups B and C, with a p-value of 0.004 ($p < 0.005$).
- **Shoulder Pain and Disability Index (SPADI):** All groups (A, B, and C) displayed significant differences in SPADI scores, with Group A showing notable improvements.

In summary, Group A exhibited significant improvements across all measured outcomes when compared to Groups B and C.

Results from One-Way ANOVA:

- **Blood Serum Cortisol:** Group A had the lowest mean post-test serum cortisol level at 14.72, indicating superior effectiveness compared to Groups B and C.
- **Shoulder External Rotation:** Group C showed the lowest mean post-test value of 68, reflecting better outcomes compared to Groups A and B.
- **Shoulder Abduction:** Group C also demonstrated the lowest mean post-test value of 68, indicating more effective results than Groups A and B.
- **Shoulder Pain and Disability Index (SPADI):** Group A achieved the lowest mean post-test SPADI score of 25.2, showing greater effectiveness than Groups B and C.
- **Ultrasonographic Results:** Group A had the lowest mean post-test ultrasonographic value of 3.62, indicating better effectiveness compared to Groups B and C.

Co-Authors Contribution: Reviewer, Translator, Evaluator role.

Conflict of Interest: No conflict of interest.

Data Availability Statement: Pre and post-test data of dependent variables including blood serum cortisol, ultrasonogram, SPADI scores, and digital goniometer.

Supplementary Materials: Institutional ethical committee approval from Faculty of Physiotherapy, Dr. M.G.R Educational and Research Institute (No. 645/2022/IEC/ACSMCH Dt.14/12/2022) and registration at Clinical

Trial Registry - India (CTRI/2024/07/069728).

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