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Effectiveness of radial extracorporeal shock-wave therapy versus ultrasound-guided low-dose intra-articular steroid injection in improving shoulder pain, function, and range of motion in diabetic patients with shoulder adhesive capsulitis

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Background: To compare the efficacy of radial extracorporeal shock-wave therapy (rESWT) vs. an ultrasound-guided low-dose intra-articular steroid injection in pain reduction and functional improvement in diabetic patients with shoulder adhesive capsulitis (AC).

Methods: This was a 2-parallel-group, active-control, assessor-blinded, randomized trial. We randomized 103 diabetic patients with shoulder AC to receive either 4 sessions of rESWT, 1 week apart (rESWT group, n = 52), or a single ultrasound-guided low-dose intra-articular steroid injection of 20 mg of triamcinolone acetonide (steroid group, n = 51). The primary outcome measure was functional improvement evaluated by the Quick Disabilities of the Arm, Shoulder and Hand (qDASH) score. Secondary outcome measures were pain evaluated by the visual analog scale score and shoulder range of motion (ROM). An assessor who was blinded to treatment assignment assessed both groups at baseline and at 4, 8, and 12 weeks thereafter.

Results: By 12 weeks, both groups demonstrated a significant reduction in the qDASH score and pain severity, as well as improvement in ROM. However, significantly improved function (qDASH score, 40.4 ± 12.9 vs. 50.5 ± 13.3; $P < .001$) and shoulder pain reduction (visual analog scale score, 1.6 ± 1.2 vs. 2.8 ± 1.7; $P < .001$) were found in the rESWT group vs. the steroid group. Similar improvement in shoulder ROM was observed in both groups.

Conclusion: At short-term follow-up, rESWT was superior to a low-dose intra-articular steroid injection in improving function and pain in diabetic patients with shoulder AC. Therefore, rESWT might be considered a safe alternative to steroid injections in diabetic patients with shoulder AC.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Shoulder; adhesive capsulitis; radial extracorporeal shock-wave therapy (rESWT); ultrasound-guided injection; steroid injections; diabetes mellitus; functional outcome; qDASH

This study followed the Ethical Standards of the Declaration of Helsinki and was approved by the Institutional Review Board and Research Ethics Committee, Faculty of Medicine, Suez Canal University (permission no. "Research 3291," December 19, 2017; Pan African Clinical Trials Registry no. PACTR201910580959319).

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Shoulder adhesive capsulitis (AC), also known as "frozen shoulder," is a common shoulder disorder characterized by a progressive and painful restriction in range of motion (ROM) that results in functional disability.[22,42] AC occurs in 2%-5% of the general population; it is 2-4 times more common in women than men and is most frequently seen in individuals aged between 40 and 60 years[34]; and about 20%-30% of cases of this condition are bilateral.[42]

Shoulder AC is common in patients with diabetes mellitus (DM).[30] The incidence of AC is 2-4 times higher in diabetic patients than in the general population, and AC affects about 20% of persons with DM.[33] Diabetic patients with AC have worse functional outcomes than their nondiabetic counterparts.[25] In Egypt, the prevalence of AC in diabetic patients is 1% in those with type 1 DM and 10% in those with type 2 DM.[41]

Radial extracorporeal shock-wave therapy (rESWT) is a noninvasive physical modality that has been used in soft-tissue disorders including lateral epicondylitis, plantar fasciitis, patellar and Achilles tendinopathy, and calcific tendinitis of the shoulder.[3,13,16,20,39] This therapy stimulates soft-tissue healing, increases regional blood flow, and induces inflammatory mediated healing processes, neovascular changes, enzyme release, reduction in inflammatory cytokines, and increased flexibility of the collagen fibers and tendons in the treated area.[36] Radial extracorporeal shock-wave therapy (ESWT) has been successfully introduced in the treatment of primary AC of the shoulder.[5,11,19,36] We are aware of only 1 study that evaluated the usefulness of ESWT in diabetic patients.[30] A systematic review of randomized clinical trials on the effectiveness of corticosteroid injections or physiotherapy for shoulder pain showed inconsistent short-term results and limited evidence for the long-term outcome.[6]

Yet, to our knowledge, no data comparing rESWT vs. intra-articular steroid injections in diabetic patients with shoulder AC are available to validate the systematic use of rESWT in shoulder rehabilitation programs. The purpose of this study was to compare the effects of 4 sessions of rESWT vs. a single intra-articular steroid injection on the short-term outcome (12 weeks) of shoulder AC in patients with DM. The primary outcome was functional improvement, whereas shoulder pain and ROM were secondary outcome measures.

Methods

Study design

This was a prospective, active-control, 2-parallel-group, assessor-blinded, randomized trial. The study was conducted at the Department of Physical Medicine, Rheumatology and Rehabilitation, Suez Canal University Hospital, Ismailia, Egypt, between December 2017 and December 2018. All participants provided an informed written consent after explaining study objectives, methods, and safety.

Participants

Inclusion criteria

Patients with controlled type 2 DM (hemoglobin A_{1c} level $< 7\%$) and unilateral AC of the shoulder were screened for inclusion. All participants underwent a standardized history, physical examination, and radiographic evaluation. The inclusion criteria were patients aged > 18 years with shoulder pain and restriction in ROM ($\geq$25% loss of ROM in $\geq$2 directions, ie, abduction, flexion, extension, external rotation, and internal rotation).[4,27] A symptom duration >3 months was required, with no radiographic findings on anteroposterior shoulder plain radiographs except for osteoporosis. No medical treatment, other than analgesics, was prescribed within the past 3 months.

Exclusion criteria

We excluded patients with uncontrolled DM, rotator cuff tears or calcification, previous intra-articular steroid injections, bilateral shoulder affection, previous surgery on the shoulder, a history of shoulder fracture, dislocation or subluxation, malignancy, bleeding disorders, severe cardiopulmonary diseases, any neuromuscular disorders, pregnancy, an implanted pacemaker, infection, septic or inflammatory arthritis, and unwillingness to participate.

Sample size

The sample size was calculated by a statistical power analysis program (G*Power software, version 3.1.9.4 for Windows; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The sample size was 50 patients per group to detect a 10-point difference in the Quick Disabilities of the Arm, Shoulder and Hand (qDASH) score between the 2 groups with 80% power ($\beta = 0.2$), a probability value of 5% ($\alpha = .05$), and medium effect size (ES, $d = 0.57$). The patients were assigned to either treatment group according to a list generated by simple randomization concealed in numbered opaque envelopes.

Interventions

Radial ESWT was administered with the BTL-5000 system (BTL Industries, Marlborough, MA, USA). Patients were seated with the shoulder passively abducted at 80°, the elbow flexed at 90°, and the forearm resting on a flat surface. Each patient received 4 applications of rESWT, 1 week apart, with 2000 impulses per session. The air pressure of the device was set to 3.5 bars; the impulses were applied at a frequency of 10 Hz. After application of the coupling gel, the shock waves were delivered to 2 separate locations.[3] The first 1000 impulses were applied in an anterior-to-posterior direction at the anterior shoulder joint, and the upper margin of the treatment zone was about 1 fingerbreadth lateral to the coracoid process. The remaining 1000 impulses, of the total 2000 impulses per session, were applied in a posterior-to-anterior direction on the posterior side of the shoulder joint located beneath the lateral border of the scapular spine.[11,36]

In the ultrasound-guided low-dose intra-articular corticosteroid injection group, patients were seated with the affected hand resting on the thigh. The posterior short-axis approach was used, in which the target was between the free edge of the labrum and the cartilage of the humeral head underneath the capsule. Once the target was obtained, a 22-gauge, 9 cm spinal injection needle was advanced with real-time ultrasonographic equipment (Samsung SonoAce Ultrasound Machine; Samsung Medison, Seoul, Republic of Korea) using a 12-MHz linear array probe. The needle was inserted just lateral to the transducer, in an oblique lateral-to-medial direction, until the needle tip entered the glenohumeral joint. We injected 2 mL of local anesthetic (lidocaine 1%) and 0.5 mL of steroid (20 mg of triamcinolone acetonide).[24]

Patients in both groups were instructed on a home-based exercise program. This program included shoulder stretching exercises and pendulum exercises, with 10 repetitions of each exercise 3 times daily.[12]

Outcome measures

All outcome measures were taken at baseline (before treatment) and at 4, 8, and 12 weeks from baseline. All assessments were performed by the same examiner who was blinded to the patients' treatment groups. The primary outcome measure was functional disability evaluated by the qDASH score. The qDASH score consists mainly of an 11-item disability and symptom scale ranging from 0 (no disability) to 100 (most severe disability). The qDASH score was shown to be reliable and valid in a patient population with various upper-extremity disorders.[7,21]

The secondary outcome measures were shoulder pain measured by a visual analog scale (VAS) and passive shoulder ROM measured by a goniometer.[22] The shoulder pain severity during the 24-hour period before assessment was recorded on a 10-cm horizontal line, on which 0 cm and 10 cm were considered no pain and worst pain, respectively. The VAS is a valid and reliable tool for the evaluation of pain outcomes in patients with shoulder AC.[8,14] Passive ROM of the affected shoulder was measured while the patient was sitting upright on a stool. Abduction, flexion, and external rotation ROMs were measured, with the patient being asked to relax as much as possible and the examiner pressing down on the clavicle and scapula with 1 hand to eliminate scapular movement during ROM measurement. External rotation ROM was checked with the shoulder in full adduction, 90° of elbow flexion, and a forearm-neutral position. Internal rotation ROM could not be measured with a goniometer because most patients could not achieve 90° of abduction, which was necessary to measure internal rotation ROM.

Statistical analysis

Data management and statistical analyses were performed using SPSS software (version 23.0; IBM, Armonk, NY, USA). According to the type of data, χ^2 and t tests were used to compare patients' characteristics. The mean and standard deviation of the qDASH score, VAS score, and ROM were measured at baseline (pretest) and at 4, 8, and 12 weeks from baseline (post-test). Both groups were compared at each time point by the t test. Repeated-measures analysis of variance (ANOVA) was used to test for the difference from pretest to post-test for the repeated outcome parameters, and this was followed by post hoc testing with Bonferroni correction. The percentage of change between the baseline (Pre) and 12-week (Post) values for outcome variables was calculated by the following equation: Change = (Post – Pre/Pre) × 100. The differences in percentages were compared between the 2 groups. The ES was calculated according to Cohen d = (Mean 2 – Mean 1)/SD_{pooled}. A small ES was defined as 0.2; medium ES, 0.5; large ES, 0.8; very large ES, 1.2; and huge ES, 2.0. To test the interaction between baseline ROM, treatment group, and outcome at 12 weeks, patients were first stratified into 2 subgroups: <100° (subgroup 1) vs. ≥100° (subgroup 2) in abduction or flexion and <45° (subgroup 1) vs. ≥45° (subgroup 2) in external rotation. Multiple linear regression analysis was then performed. $P < .05$ was considered significant.

Results

We screened 123 diabetic patients with AC for the study. Of these patients, 15 did not meet the inclusion criteria and were excluded: 5 had rotator cuff problems (impingement and/or tear), 4 had calcific tendinitis, 3 had secondary arthritis, 2 underwent a stroke, and 1 refused to participate. In addition, 5 patients were lost to follow-up after the first encounter, 2 from the rESWT group and 3 from the steroid group, and were excluded from final analysis. So, the final sample was 103 diabetic patients with shoulder AC: 52 in the rESWT group and 51 in the steroid group (Fig. 1).

The mean age was 55.87 ± 6.7 years and 57.96 ± 9.0 years in the rESWT and steroid groups, respectively. Overall, 79 women and 24 men were included in the study. The symptom duration ranged from 6-30 months in both study groups. All patients had unilateral shoulder affection (68 right and 35 left) and well-controlled DM (hemoglobin A_{1c} level < 7%). No significant difference was found between the 2 groups regarding demographic characteristics (Table I).

Table II lists the outcome parameters for patients who completed the 12-week follow-up in both groups. At baseline, there was no significant difference between the 2 groups in the initial values of the VAS score for pain, qDASH score, and shoulder ROM. By the 12th week, both groups demonstrated a significant reduction in shoulder pain, functional disability, and passive ROM ($P < .001$). Comparing both groups at the 12th week, we found a significantly lower mean VAS score for pain and qDASH score in the rESWT group vs. the steroid group ($P < .001$). However, no significant difference in ROM values was noted between the 2 groups ($P > .05$) (Table II).

Change (percentage) in the VAS score, qDASH score, and ROM and the ES for both groups are detailed in Table III. In the rESWT group, the VAS score for pain changed by –82.6% (ES, 4.9), from 9.2 ± 1.8 to 1.6 ± 1.2 ($P < .001$), and the qDASH score changed by –42.9% (ES, 2.2), from 70.8 ± 14.3 to 40.4 ± 12.9 ($P < .001$). In the steroid group, the VAS score for pain changed by –69.2% (ES, 3.1), from 9.1 ± 2.3 to 2.8 ± 1.7 ($P < .001$), and the qDASH score changed by –32.8% (ES, 1.4), from 75.1 ±

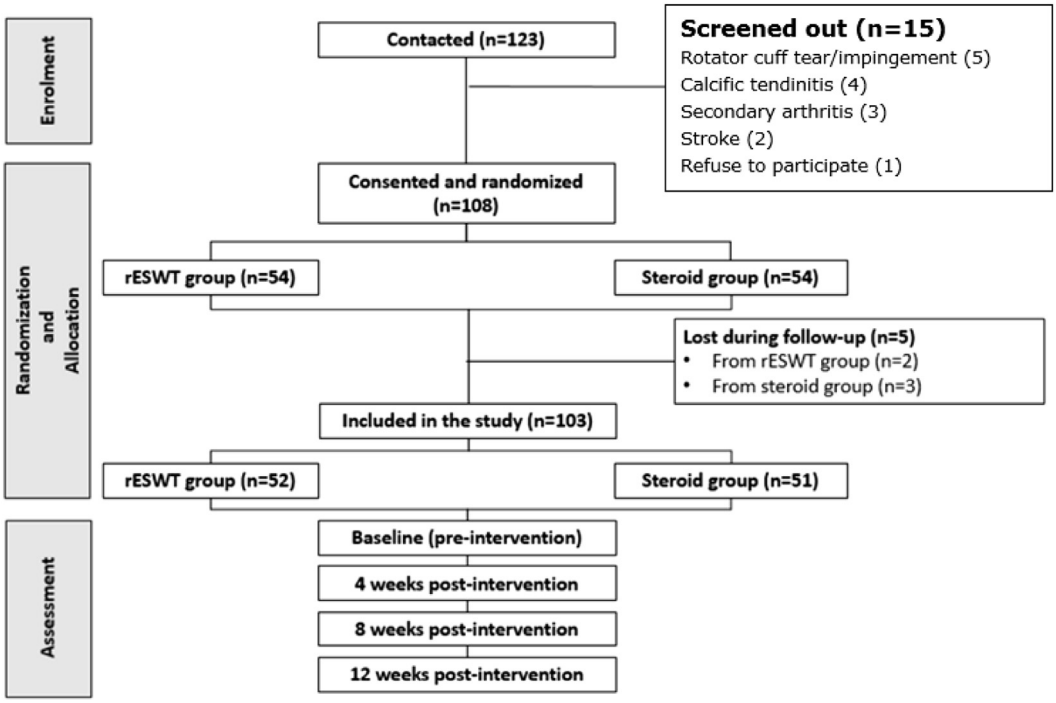

Figure 1 Flowchart of study population. *rESWT*, radial extracorporeal shock-wave therapy.

Table I Demographic data of patients in both groups

Characteristic	rESWT group (n = 52)	Steroid group (n = 51)	*P* value
Age, mean ± SD, yr	55.9 ± 6.7	57.9 ± 9.0	.20
Sex: male/female, n	15/37	9/42	.18
Disease duration, median (range), mo	7 (6-29)	12 (6-30)	.31
Affected side: right/left, n	31/21	37/14	.17
HbA_{1c} level, mean ± SD, %	6.6 ± 0.36	6.5 ± 0.22	.09

rESWT, radial extracorporeal shock-wave therapy; *SD*, standard deviation; *HbA_{1c}*, hemoglobin A_{1c}.
The steroid group received an intra-articular ultrasound-guided triamcinolone acetonide injection.

20.5 to 50.5 ± 13.3 ($P < .001$). The rESWT group showed greater reductions in VAS scores (ES, 0.8) and qDASH scores (ES, 0.8) than the steroid group ($P = .025$ for VAS score and $P = .048$ for qDASH score). In contrast, both groups showed insignificant differences regarding change (percentage) in abduction, flexion, and external rotation ROM with small ES values (Table III).

Primary outcome measure

Repeated-measures ANOVA showed a significant reduction in the qDASH score during follow-up in both groups ($P < .001$). The rESWT group showed significantly lower mean qDASH scores at 4 weeks (44.1 ± 13.0), 8 weeks (39.9 ± 12.9), and 12 weeks (40.4 ± 12.9) vs. baseline (70.8 ± 14.3) ($P < .001$). In the steroid group, mean VAS scores were significantly lower at 4 weeks (54.9 ± 13.1), 8 weeks (51.6 ± 12.6), and 12 weeks (50.5 ± 13.3) vs. baseline (75.1 ± 10.5) ($P < .001$). There was a significant improvement in the qDASH score in the rESWT group vs. the steroid group at all time points ($P < .001$) (Fig. 2, Table IV).

Secondary outcome measures

Repeated-measures ANOVA showed a significant reduction in the VAS score for shoulder pain during follow-up in both groups ($P < .001$). Regarding post hoc comparisons, the rESWT group showed significantly lower mean VAS scores at 4 weeks (3.4 ± 1.6), 8 weeks (2.8 ± 1.2), and 12 weeks (1.6 ± 1.2) vs. baseline (9.2 ± 1.8) ($P < .001$). In the steroid group, mean VAS scores were significantly lower at 4 weeks (5.0 ± 1.6), 8 weeks (3.8 ± 1.5), and 12 weeks (2.8 ± 1.7) vs. baseline (9.1 ± 2.3) ($P < .001$). Comparison

Table II Outcome parameters at baseline and after intervention in both groups

Outcome parameter	Baseline	12 weeks	*P* value*
VAS pain score			
rESWT group (n = 52)	9.2 ± 1.8	1.6 ± 1.2	<.001
Steroid group (n = 51)	9.1 ± 2.3	2.8 ± 1.7	<.001
P value		<.001†	
QuickDASH score			
rESWT group (n = 52)	70.8 ± 14.3	40.4 ± 12.9	<.001
Steroid group (n = 51)	75.1 ± 20.5	50.5 ± 13.3	<.001
P value		<.001†	
Abduction ROM, °			
rESWT group (n = 52)	101 ± 24	131 ± 21	<.001
Steroid group (n = 51)	103 ± 24	127 ± 22	<.001
P value		.416†	
Flexion ROM, °			
rESWT group (n = 52)	106 ± 14	132 ± 12	<.001
Steroid group (n = 51)	107 ± 25	127 ± 21	<.001
P value		.209†	
External rotation ROM, °			
rESWT group (n = 52)	45 ± 13	61 ± 12	<.001
Steroid group (n = 51)	48 ± 14	65 ± 13	<.001
P value		.149†	

VAS, visual analog scale; *rESWT*, radial extracorporeal shock-wave therapy; *QuickDASH*, Quick Disabilities of the Arm, Shoulder and Hand; *ROM*, range of motion.
Data are expressed as mean ± standard deviation. Data analysis within groups is expressed as *P* values.
* *P* value comparing baseline and 12 weeks.
† *P* value comparing both groups at 12 weeks.

Table III Percentage of change in VAS, QuickDASH, and ROM parameters and effect size in both groups

Outcome measure	Change, %			Effect size (Cohen *d*)		
	rESWT group	Steroid group	*P* value	rESWT group	Steroid group	Between groups
VAS pain score	−82.6	−69.2	.025	4.9	3.1	0.8
QuickDASH score	−42.9	−32.8	.048	2.2	1.4	0.8
ROM, °						
Abduction	29.3	23.7	.20	1.3	1.0	0.2
Flexion	24.4	18.8	.10	2.0	0.9	0.3
External rotation	36.4	35.6	.81	1.3	1.2	0.3

VAS, visual analog scale; *QuickDASH*, Quick Disabilities of the Arm, Shoulder and Hand; *ROM*, range of motion; *rESWT*, radial extracorporeal shock-wave therapy.
Data analysis within groups is expressed as *P* values.

between the rESWT and steroid groups via the *t* test showed a significant improvement in the VAS score in the rESWT group vs. the steroid group at all time points ($P < .001$) (Fig. 2, Table IV).

Repeated-measures ANOVA showed a significant improvement in passive abduction ROM during follow-up in both groups ($P < .001$). Regarding post hoc comparisons, the rESWT group showed significant improvement in mean abduction ROM at 4 weeks (127° ± 16°), 8 weeks (127° ± 13°), and 12 weeks (131° ± 21°) vs. baseline (101° ± 24°) ($P < .001$). In the steroid group, there was also a significant improvement in mean abduction ROM at 4 weeks (125° ± 21°), 8 weeks (125° ± 22°), and 12 weeks (127° ± 22°) vs. baseline (103° ± 24°) ($P < .001$). The comparison between the rESWT and steroid groups via the *t* test showed insignificant differences between the 2 groups regarding abduction ROM at all time points ($P > .05$) (Fig. 3, Table IV).

Repeated-measures ANOVA showed a significant improvement in passive flexion ROM during follow-up in both groups ($P < .001$). Regarding post hoc comparisons, the rESWT group showed significant improvement in mean

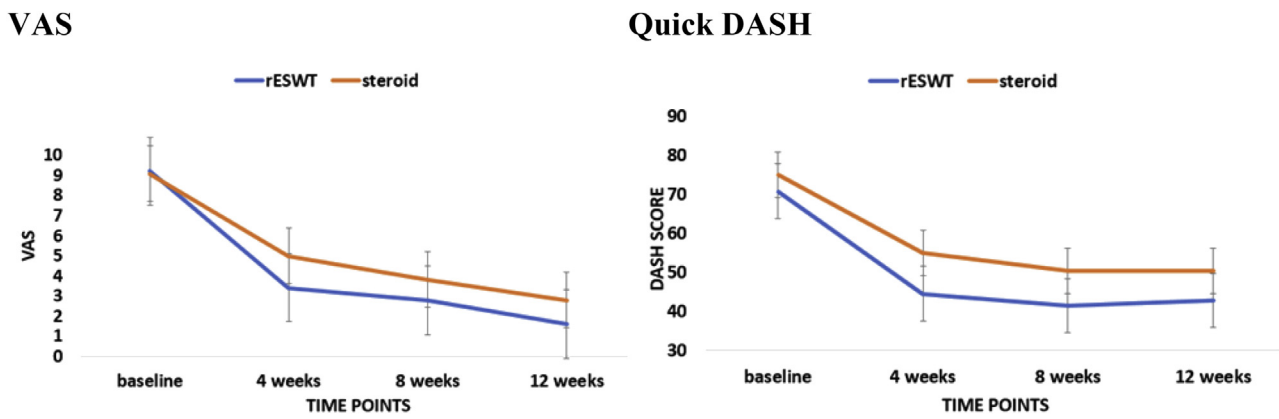

Figure 2 Shoulder pain and functional shoulder scores after treatment with radial extracorporeal shock-wave therapy *(rESWT)* and intra-articular steroids. Both groups had equal pain and functional scores at baseline ($P = .67$ and $P = .221$, respectively). Comparison between the rESWT and steroid groups via the *t* test showed significant improvements in visual analog scale *(VAS)* scores in the rESWT group vs. the steroid group at all time points ($P < .001$). In addition, there was a significant reduction in the Quick Disabilities of the Arm, Shoulder and Hand *(DASH)* score during follow-up in both groups ($P < .001$).

Table IV VAS score, QuickDASH score, and ROM in study participants

Outcome measure	Baseline	4 weeks	8 weeks	12 weeks	*P* value (ANOVA)
VAS pain score					
rESWT group	9.2 ± 1.8	3.4 ± 1.6	2.8 ± 1.2	1.6 ± 1.2	<.001
Steroid group	9.1 ± 2.3	5.0 ± 1.6	3.8 ± 1.5	2.8 ± 1.7	<.001
P value	.806	.0001	.0003	.0001	
qDASH score					
rESWT group	70.8 ± 14.3	44.1 ± 13.0	39.9 ± 12.9	40.4 ± 12.9	<.001
Steroid group	75.1 ± 10.5	54.9 ± 13.1	51.6 ± 12.6	50.5 ± 13.3	<.001
P value	.085	.0001	.0001	.0002	
Forward flexion, °					
rESWT group	106 ± 14	129 ± 13	130 ± 13	132 ± 12	<.001
Steroid group	107 ± 25	126 ± 19	126 ± 19	127 ± 21	<.001
P value	.741	.278	.227	.206	
Abduction, °					
rESWT group	101 ± 24	127 ± 16	127 ± 13	131 ± 21	<.001
Steroid group	103 ± 24	125 ± 21	125 ± 22	127 ± 22	<.001
P value	.597	.563	.575	.416	
External rotation, °					
rESWT group	45 ± 13	63 ± 19	60 ± 18	61 ± 12	<.001
Steroid group	48 ± 14	62 ± 14	64 ± 14	65 ± 13	<.001
P value	.274	.857	.853	.931	

VAS, visual analog scale; *QuickDASH*, Quick Disabilities of the Arm, Shoulder and Hand; *ROM*, range of motion; *ANOVA*, analysis of variance; *rESWT*, radial extracorporeal shock-wave therapy.

flexion ROM at 4 weeks (129° ± 13°), 8 weeks (130° ± 13°), and 12 weeks (132° ± 12°) vs. baseline (106° ± 14°) ($P < .001$). In the steroid group, there was also a significant improvement in mean flexion ROM at 4 weeks (126° ± 19°), 8 weeks (126° ± 19°), and 12 weeks (127° ± 21°) vs. baseline (107° ± 25°) ($P < .001$). The comparison between the rESWT and steroid groups via the *t* test showed insignificant differences between the 2 groups regarding flexion ROM at all time points ($P > .05$) (Fig. 3, Table IV).

Repeated-measures ANOVA showed a significant improvement in passive external rotation ROM during follow-up in both groups ($P < .001$). Regarding post hoc comparisons, the rESWT group showed significant improvement in mean external rotation ROM at 4 weeks (63° ± 19°), 8 weeks (60° ± 18°), and 12 weeks (61° ± 12°) vs. baseline (45° ± 13°) ($P < .001$). In the steroid group, there was also significant improvement in mean external rotation ROM at 4 weeks (62° ± 14°), 8 weeks

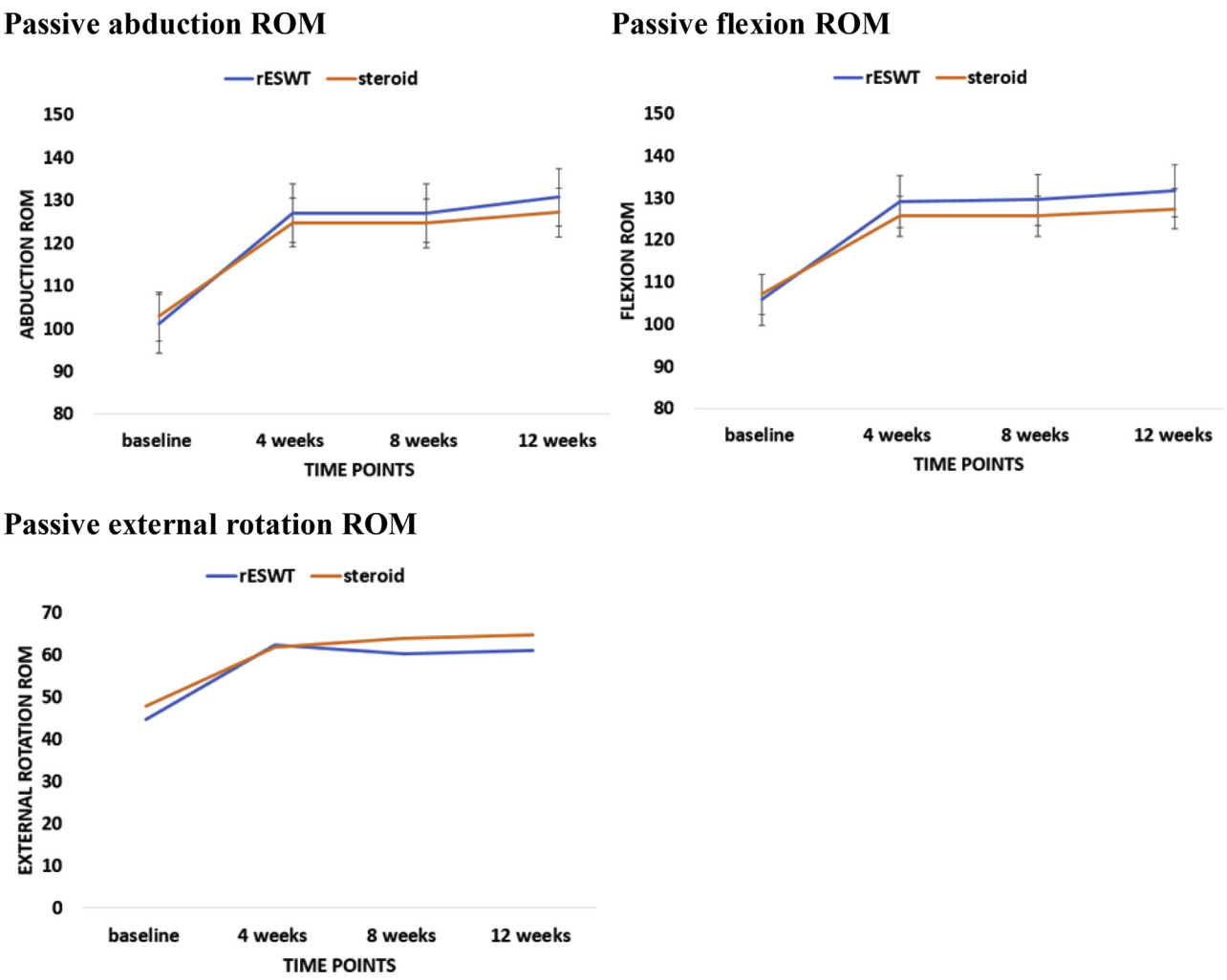

Figure 3 Shoulder passive range of motion *(ROM)* (in degrees) throughout treatment with radial extracorporeal shock-wave therapy *(rESWT)* and intra-articular steroids. Both groups had equal passive range of motion in all directions before treatment. Significant improvement occurred in both groups in all directions compared with baseline ($P < .001$). However, there was no significant difference between groups at any time point.

(64° ± 14°), and 12 weeks (65° ± 13°) vs. baseline (48° ± 14°) ($P < .001$) The comparison between the rESWT and steroid groups via the *t* test showed insignificant differences between the 2 groups regarding external rotation ROM at all time points ($P > .05$) (Fig. 3, Table IV).

Stratification of the patients according to baseline ROM showed significantly higher improvement in ROM in abduction and flexion in patients with more stiffness at baseline (<100°) in the rESWT group compared with the steroid group. Although there was a trend toward better improvement in external rotation in the steroid group, this did not reach statistical significance (Tables V and VI).

Adverse effects

The application of rESWT was associated with mild to moderate pain (VAS score, 5.5 ± 2.8) immediately after

Table V Distribution of 3-month ROM by study group and by baseline ROM

Baseline ROM	3-mo ROM, °	
	rESWT group	Steroid group
Passive abduction		
<100°	124 ± 17	111 ± 23
≥100°	134 ± 11	138 ± 13
Overall	131 ± 21	127 ± 22
Passive external rotation		
<45°	54 ± 17	61 ± 20
≥45°	68 ± 17	69 ± 15
Overall	61 ± 12	65 ± 13
Passive flexion		
<100°	133 ± 10	102 ± 12
≥100°	131 ± 13	134 ± 17
Overall	132 ± 12	127 ± 21

ROM, range of motion; *rESWT*, radial extracorporeal shock-wave therapy.

Table VI Multiple linear regression analysis for testing effect of treatment modality (rESWT vs. steroid) on 3-month range of motion

Main effect model*	Passive abduction		Passive external rotation		Passive flexion	
	β	*P* value	β	*P* value	β	*P* value
Intercept	110.56	<.001	66.67	<.001	102.0	<.001
Group (rESWT vs. steroid)	13.02	.022†	−12.58	.022†	30.50	<.001†
Subgroup (baseline range of motion)*	27.30	<.001†	9.05	.082	32.44	<.001†
Interaction (Group × Range)	−17.12	.015†	4.36	.546	−34.04	<.001†
Simple effect models*						
Subgroup 1‡						
Intercept	110.56	<.001	—	—	102.0	<.001
Group (rESWT vs. steroid)	13.02	.086	—	—	30.50	<.001†
Subgroup 2‡						
Intercept	137.86	<.001	—	—	134.44	<.001†
Group (rESWT vs. steroid)	−4.107	.201	—	—	−3.54	.412

rESWT, radial extracorporeal shock-wave therapy.
* Dependent variable: passive motion at 3 months.
† Statistically significant ($P < .05$).
‡ Baseline range of motion of <100° (subgroup 1) vs. ≥100° (subgroup 2) in abduction or flexion and <45° (subgroup 1) vs. ≥45° (subgroup 2) in external rotation.

treatment in about one-third of the patients (n = 18, 34.6%); this lasted for only 1-2 days and did not interrupt the therapy. No other relevant adverse effects were reported in either group.

Discussion

AC of the shoulder is a common comorbidity in diabetic patients with a significant impact on patients' quality of life and worse outcomes than nondiabetic patients.[25,37,41] A recent systematic review found a very low quality of evidence on nonsurgical interventions for managing shoulder AC in diabetic patients, including physiotherapeutic interventions (exercise, modalities, mobilization), nonsteroidal anti-inflammatory drugs, and/or corticosteroid injections.[29] Radial ESWT has been applied successfully for the treatment of several musculoskeletal complaints.[3,13,16,19,38] Our findings indicate that rESWT is an effective treatment modality for shoulder AC in diabetic patients in comparison with a single ultrasound-guided low-dose intra-articular steroid injection. Although both treatment groups showed functional outcome improvements after treatment, patients who received rESWT showed better improvement in the qDASH score and pain than the steroid group with similar improvement in ROM in both groups.

The effectiveness of rESWT in diabetic patients with shoulder AC is consistent with the findings of recent studies performed in primary AC.[5,11,19,36] Santoboni et al[30] reported functional improvement in shoulder AC in 51 diabetic patients after rESWT. However, this was an observational and uncontrolled trial.

The molecular basis of the efficacy of rESWT in shoulder AC in diabetic patients has not been fully elucidated. It might be explained by the pathologic process of AC in which a combination of synovial inflammation and capsular fibrosis occurs.[1,26,35] ESWT significantly stimulates soft-tissue healing and increases blood flow to the affected site.[17] This accelerated healing is accompanied by the increased expression of endothelial nitric oxide synthase and the generation of new vessels in the wound tissues.[10,17] Similar findings were reported in studies of patients with tendinopathy treated by ESWT.[38] The greater improvement in ROM in the rESWT group with more restricted ROM at baseline compared with the steroid group suggests that treatment should be tailored according to the stage of AC.[22,23]

So far, the mechanism of analgesia produced by ESWT is uncertain. Decreased levels of substance P and calcitonin gene-related peptide in dorsal root ganglia were found after treatment with ESWT in rabbit femurs and rat skin, respectively.[9,32] This might explain the pain relief after ESWT application.

A low-dose steroid was chosen to minimize the systemic side effects of steroid injections in our diabetic patients. The rapid improvement in shoulder pain, function, and ROM within the first 4 weeks that was sustained until 12 weeks supports the efficacy of a low-dose intra-articular steroid injection under ultrasound guidance in diabetic patients with shoulder AC. This finding is consistent with the results of several studies comparing low doses and high doses in primary and mixed cases of AC of the shoulder.[15,28,40] In addition, several studies reported greater efficacy with injection under ultrasound guidance than blind injection for shoulder AC.[2,18,31,40]

Our study had several limitations. The follow-up period was short, lasting only 12 weeks. A longer follow-up period is necessary for treatment efficacy and safety evaluations. In addition, we used a positive control group treated with steroids to determine the contribution of rESWT treatment. Future studies should include a negative control group.

Conclusion

Our patients showed functional outcome improvements regardless of whether they were treated with rESWT or a steroid, but those who received rESWT had better functional outcome improvements. Radial ESWT can be an alternative treatment, at least in the short term, for diabetic patients with AC of the shoulder. In addition, diabetic patients with shoulder AC can take advantage of rESWT because of its noninvasive, safe nature; low costs; and the lack of significant adverse events during treatment.

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