In the Treatment of Subacromial Impingement Syndrome Is Extra Corporeal Shock Wave Therapy Combined With Isokinetic Exercise for Rotator Cuff More Effective Than Extra Corporeal Sh...

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Is Extracorporeal Shockwave Therapy Combined With Isokinetic Exercise More Effective Than Extracorporeal Shockwave Therapy Alone for Subacromial Impingement Syndrome? A Randomized Clinical Trial

STUDY DESIGN: Single-blind randomized trial.

BACKGROUND: Extracorporeal shockwave therapy (ESWT) has been shown to produce good results in the treatment of subacromial impingement syndrome (SAIS). The efficacy of a combined administration of ESWT and isokinetic exercise (IE) has not yet been studied.

OBJECTIVES: To evaluate the efficacy of focused ESWT combined with IE for the rotator cuff versus focused ESWT alone in the treatment of SAIS. The secondary objective was to assess the isokinetic torque recovery (external rotation at 210°/s, 180°/s, and 120°/s).

METHODS: Thirty participants with SAIS were randomly assigned to a focused-ESWT group or focused ESWT–plus-IE group. Subjects of both groups received 3 treatment sessions of focused ESWT over a period of 10 days. Participants in the second group also received IE for 10 therapy sessions. Outcome measures were the Constant-Murley score (CMS), the visual analog scale (VAS), and isokinetic parameters (peak torque and total work calculated from 5 repetitions) measured with the isokinetic test. Subjects were assessed at baseline, 10 days after the last treatment session with focused ESWT, and after 2 months of follow-up.

RESULTS: At 2 months posttreatment, participants in the focused ESWT–plus-IE group showed significantly less pain (focused-ESWT VAS, 3.4 ± 0.8 versus focused ESWT–plus-IE VAS, 1.5 ± 0.5; *P*<.001) and greater improvement in functionality (focused-ESWT CMS, 75.9 ± 6.7 versus focused ESWT–plus-IE CMS, 92.1 ± 6.3; *P*<.001) and muscle endurance than the subjects in the focused-ESWT group.

CONCLUSION: In subjects with SAIS, combined administration of focused ESWT and IE for the rotator cuff resulted in greater reduction of pain, as well as superior functional recovery and muscle endurance in the short to medium term, compared with ESWT alone.

LEVEL OF EVIDENCE: Therapy, 2b. Trial registration: unregistered 2011 trial. *J Orthop Sports Phys Ther 2016;46(9):714-725. Epub 5 Aug 2016. doi:10.2519/jospt.2016.4629*

KEY WORDS: *Constant-Murley score, isokinetic parameters, muscle torque, physical therapy, rotator cuff tendinopathy, shoulder pain, visual analog scale*

Rotator cuff tendinopathy includes external or internal impingement, tendinitis, tendinosis with degeneration, and partial-thickness tendon tears.[22] The mechanisms of rotator cuff tendinopathy have been classified as extrinsic, intrinsic, or a combination of both.[62] Extrinsic mechanisms are those causing compression of the rotator cuff tendons, and intrinsic mechanisms are those associated with degeneration of the rotator cuff tendon.[72] Neer[60] proposed an extrinsic mechanism for the etiology of rotator cuff tendinopathy, with compression of the rotator cuff tendons and associated tissues between the anteroinferior corner of the acromion and the greater tuberosity of the humerus,[19] and coined the term *subacromial impingement syndrome* (SAIS).[61] The diagnosis of SAIS inherently implies an extrinsic compression mechanism due to narrowing of the

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subacromial space, which may not accurately represent all rotator cuff tendon pathology.[72] A unique extrinsic mechanism, internal impingement, described particularly in overhead athletes,[6,48] is attributed to compression of the posterior articular surface of the tendons between the humeral head and glenoid when the arm is in full external rotation, abduction, and extension,[15] and is not related to subacromial-space narrowing. In contrast to extrinsic mechanisms of rotator cuff tendinopathy, Codman and Akerson[9] postulated an intrinsic mechanism due to degeneration within the tendon with tensile/shear overload, including alterations in biology, mechanical properties, morphology, and vascularity, confounded by aging.[75,78] Subacromial impingement syndrome is characterized by pain on the anterior/posterior and lateral shoulder, extended to the deltoid and biceps muscles at rest and during abduction; forced internal rotation; and resisted motions. Several causative mechanisms have been proposed, such as continuous lesions during the glenohumeral joint movement caused by subacromial contact, subcoracoid space, coracoacromial ligament, and coracoacromial articulation; alteration of acromial morphology[3]; alteration of arterial vascularization of the humeral head[24,70]; overuse syndrome; or alterations of the tensile properties of the supraspinatus tendon.[39] Moreover, scapular dyskinesia can be considered another important mechanism of SAIS.[29,56]

Management of SAIS includes numerous interventions, depending on the severity of pain and the stage of the tendon lesion as described by Neer[61]: stage 1, the presence of edema and hemorrhage; stage 2, deterioration of the tendon and bursa; or stage 3, bone spurs and partial- or full-thickness tendon rupture. Analgesic and nonsteroidal anti-inflammatory drugs,[2] steroid injections,[5] and physical therapy treatment techniques have often been reported, with mixed results.[74,80] Systematic reviews have suggested that physical therapy has not provided unequivocal results because of the notable variability of the underlying lesions.[26,47,79] However, according to the recommendations from the Philadelphia Panel, an expert panel on selected rehabilitation interventions for shoulder pain, therapeutic exercise was an acceptable intervention for SAIS.[45,64] The large, unrestricted range of motion (ROM) of the glenohumeral joint and limited inherent bony stability necessitate dynamic muscular stabilization to ensure normal joint arthrokinematics. Although pain can still reduce their efficacy, rehabilitative exercise approaches for the treatment of SAIS include stretching, isometric and isotonic exercises, Codman exercises, and active and passive ROM exercises.[13,56] Isometric and isotonic exercises are designed to strengthen the weakened rotator cuff musculature, thus restoring its ability to counteract the action of the deltoid muscle.[52,58] Scapular-stability exercises are included in the rehabilitation of people with SAIS because electromyographical studies have highlighted increased activity in the upper trapezius, with decreased activity in the serratus anterior and the middle and lower fibers of the trapezius, and asynchronous timing deficits in subjects with SAIS.[52,57] Application of isokinetic exercise (IE) and testing for the upper extremity may be very useful, due to the demanding muscular work required in daily activities.[53,55]

Extracorporeal shockwave therapy (ESWT) has been suggested as a beneficial treatment for SAIS that may decrease the need for surgery.[30,49,81] Shockwaves are defined as transient pressure oscillations that propagate in 3 dimensions and typically bring about a clear increase in pressure within a few nanoseconds.[38] The process involves very rapidly rising positive pressure impulses from 5 to 120 MPa in around 5 nanoseconds, followed by a decrease to negative pressure values of −20 MPa.[77] The theoretical benefits are reduction of calcification, promotion of soft tissue healing, and inhibition of pain receptors to achieve relief from pain.[31,51] There are 2 types of ESWT, focused and radial, that differ in how they penetrate or dissipate at the skin. Focused waves target tissues with higher penetration power and impact than those of radial waves, which are directed radially at the skin.[20] To date, many studies on employment of ESWT in treating tendinopathies have been published.[8,12,25,28,30,31,33,36,49,51,63,67,73,76,81]

Different studies on rehabilitation after ESWT have verified the efficacy of eccentric exercises; however, this is limited to the treatment of Achilles tendinopathy and jumper's knee.[43,68,69] The objective of the present study was to test ESWT for SAIS associated with isokinetic rehabilitation to correct related muscle dysfunction. Some studies have suggested that active and passive exercise may be useful in the management of SAIS.[13,47] Furthermore, scapular and humeral kinematic abnormalities can cause dynamic narrowing of the subacromial space, leading to rotator cuff tendon compression secondary to superior translation of the humeral head or aberrant scapular motion that causes the acromion to move inferiorly.[29,52] The muscle-strengthening exercise is usually integrated in the treatment program to maintain the regained ROM, prevent disuse atrophy, and restore muscle function. Malliou and colleagues[53] compared different training methods for improving muscular performance in the shoulder rotator cuff. They determined that isokinetic strengthening is the most effective method of altering strength ratios. Beneka and colleagues[1] found that the isokinetic method was more effective at increasing rotator strength. The restoration of imbalances may be due to strengthening of the internal and external rotators. To the authors' knowledge, no studies to date have tested the possible benefits of ESWT and IE for SAIS. The aim of this study was to compare the effectiveness of 2 protocols for the treatment of SAIS (focused ESWT alone and focused ESWT combined with IE) in a single-blind randomized trial. The 2 approaches were compared using traditional assessment scores (visual analog scale [VAS] and Constant-Murley score [CMS]).[11,65] The secondary objective was to assess the isokinetic torque recovery (external rotation at 210°/s, 180°/s, and 120°/s).

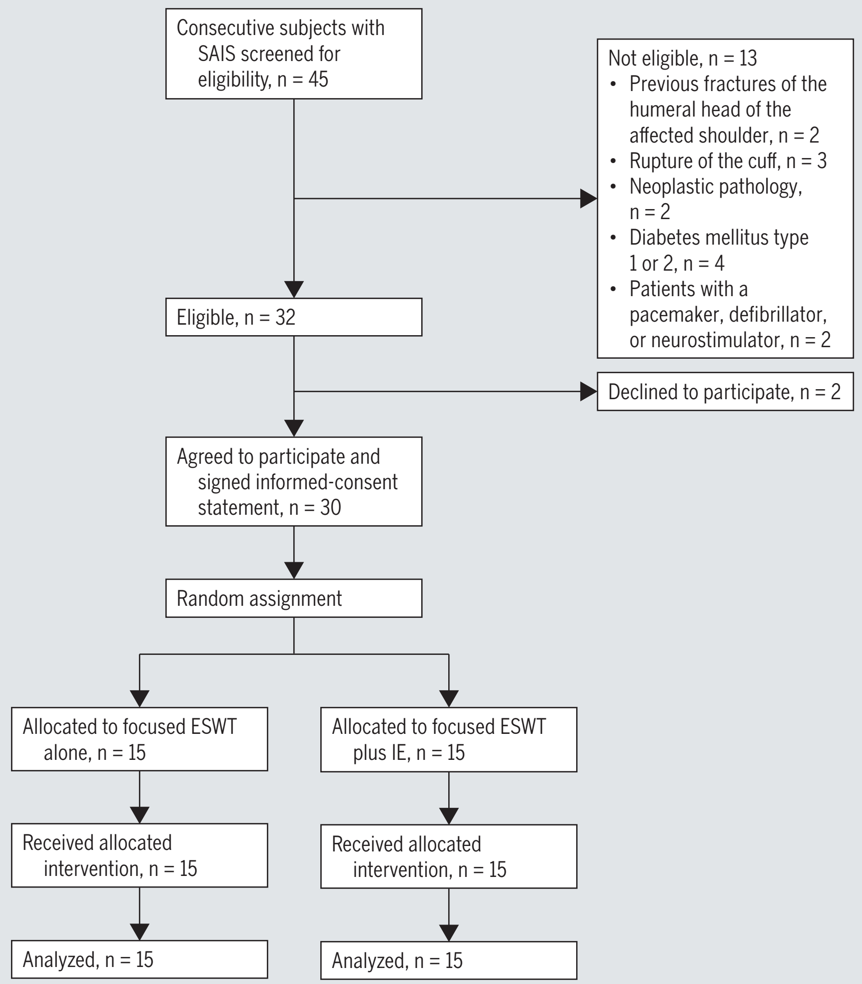

FIGURE. Flow diagram of subject retention and recruitment for focused ESWT alone and ESWT plus IE for SAIS. Abbreviations: ESWT, extracorporeal shockwave therapy; IE, isokinetic exercise; SAIS, subacromial impingement syndrome.

METHODS

Setting and Participants

The present study was a single-blind randomized trial conducted according to the Declaration of Helsinki, the guidelines for good clinical practice, and the Consolidated Standards of Reporting Trials (CONSORT) statement guidelines.[71] The Institutional Review Board of the University of Foggia (Foggia, Italy) approved the study protocol. Consecutive outpatients older than 18 years of age and with pain in the shoulder for at least 4 weeks prior to the study were potentially eligible to participate in this study. Individuals who had clinical signs of unilateral SAIS, attending the Department of Physical Medicine and Rehabilitation at OORR Hospital (University of Foggia) from January 2011 to July 2011, were invited to participate in the study and were screened for study eligibility.

Diagnostic criteria for SAIS were the presence of shoulder pain, pain on abduction of the shoulder with painful arc, a positive impingement sign (Hawkins sign),[32] and a positive impingement test (relief of pain within 15 minutes after injection of local anesthetic [bupivacaine 5 mL] into the subacromial space). All patients were also evaluated by radiography, ultrasonography, or magnetic resonance imaging (MRI) of the shoulder (for MRI, extremely low acromiohumeral, coracohumeral, and coracoclavicular intervals were quantitative measures for SAIS diagnosis)[35,42] to confirm the diagnosis of stage 1 (presence of edema and hemorrhage) or 2 (deterioration of the tendon and bursa) SAIS, according to Neer's classification.[61] We used the diagnostic criteria for ultrasonography described by Naredo and colleagues.[59] This technique included a dynamic examination of the supraspinatus tendon obtained by moving the patient's arm from a neutral position to 90° of abduction in order to detect encroachment of the acromion into the rotator cuff. Subjects were excluded from the study if they met any of the following criteria: shoulder affected bilaterally, receiving anesthetic or corticosteroid injections within 4 weeks of study enrollment, surgery or previous fractures of the ipsilateral humeral head of the affected shoulder, a history of acute trauma, known osteoarthritis in the acromioclavicular or glenohumeral joints (identified by conventional radiography to assess acromion shape), calcifications exceeding 2 cm in the rotator cuff tendons or signs of a rupture of the cuff, cervical myofascial pain syndrome, radicular pain, diabetes mellitus type 1 or 2, thyroid dysfunctions, pacemaker, neurological pathologies, and anxious depressive syndromes.

Concealed allocation was performed with random numbers generated before the beginning of the study. Before the study commenced, a random-integer generator generated 100 random integers, and individual, sequentially numbered index cards with the random assignments were folded and placed in sealed, opaque envelopes. A physician member of the research team (A.N.), who was blinded to the baseline examination findings, opened the envelopes to allocate the interventions according to group assignments.

TABLE 1 Baseline Demographic and Clinical Characteristics of the Sample by Treatment Group*

	ESWT (n = 15)	ESWT Plus IE (n = 15)
Age, y	39.4 ± 3.9 (32-45)	41.1 ± 6.0 (31-52)
Time since onset of pain, mo	7.5 ± 4.2 (2-16)	7.6 ± 3.8 (3-15)
Sex, n		
Female	9	7
Male	6	8
Diagnosis, n		
SAIS, Neer stage 1	8	7
SAIS, Neer stage 2	7	8

Abbreviations: ESWT, extracorporeal shockwave therapy; IE, isokinetic exercise; SAIS, subacromial impingement syndrome.
**Values are mean ± SD (range) unless otherwise indicated.*

Outcome Measures

All participants underwent clinical examination that was performed by 1 physician, who was blinded to group assignment, using the VAS[65] and CMS as primary outcome measures[11] and the isokinetic test as the secondary outcome measure.[40]

The VAS, a 10-cm line with a left end point of "no shoulder pain" and a right end point of "worst pain ever," was used to measure pain[65] during external rotation and abduction movements of the affected shoulder. In the acute pain setting, the VAS has been shown to have very good test-retest reliability (intraclass correlation coefficient [ICC] = 0.99).[4] The VAS is generally accepted as a valid measure of acute pain, with good construct validity.[41,84] At a consensus meeting of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), the results of several studies suggested that a score change of approximately 1 point or 15% to 20% represents the minimal clinically important difference (MCID) for the VAS and for similar numeric rating scales (0-10) for pain intensity.[14]

The CMS is a 100-point scoring system of which 35 points are from patient self-report of pain and function and the remaining 65 points are allocated to objective assessment of ROM and strength. The self-report assessment includes a single item for pain (15 points) and 4 items for activities of daily living (work, 4 points; recreation, 4 points; sleep, 2 points; and ability to work at various levels, 10 points). The objective assessment includes ROM (forward elevation, 10 points; external rotation, 10 points; internal rotation, 10 points; abduction, 10 points) and power (scoring based on the number of pounds of pull the patient can resist in abduction, to a maximum of 25 points).[11] The CMS has good psychometric properties, reflecting shoulder function with accuracy, test-retest reliability (ICC = 0.80),[10] and reproducibility.[23] Unfortunately, to date, there are no studies to provide data on the MCID for the CMS, despite the fact that the error estimates (95% confidence interval of the standard error of measurement [SEM], ±17.7)[10] and responsiveness (standardized response mean, 0.59),[44] that is, the ability of a measure to detect change over time, have been reported.

Isokinetic testing has been advocated as a reliable method for quantifying many parameters of shoulder muscle function.[27,40] Testing should be comfortable and safe, and result in reproducible and accurate measurements of specific functions, such as muscle torque of the rotator cuff. We evaluated the peak torque and total work calculated from 5 repetitions of external rotation with the arm in the scapular plane (45° of abduction, 30° of flexion, and the elbow in 90° of flexion), to compare the results of the isokinetic test (concentric testing) after 5 sessions at each of 3 different speeds (120°/s, 180°/s, and 210°/s). The position chosen for isokinetic assessment of shoulder rotators allowed the best reproducibility and reliability for internal and external rotators.[21] These speeds were chosen to avoid further tendon impairments with higher resistance. All subjects performed the isokinetic test using the HUMAC NORM for CYBEX dynamometer (Computer Sports Medicine Inc, Stoughton, MA). Patient stabilization, in a seated position, was achieved with 4 Velcro straps: 1 across the hips, 2 across the chest, and 1 around the forearm.[17] The unaffected side was tested first, followed by the affected side. Peak torque and total work calculated from 5 repetitions were used to assess muscular impairment. All isokinetic testing was conducted by 1 investigator (G.V.), who was blinded to group allocation. The results are presented as the difference between mean values of the affected and the unaffected side.

Interventions

After baseline evaluation, both treatment groups were treated with 3 sessions over 10 days (ie, each session was followed by a 3-day interval) of medium-energy (0.12 mJ/mm^2) focused ESWT, administered with an electrohydraulic lithotripter (EvoTron; High Medical Technologies AG, Lengwil, Switzerland). We chose 3 ESWT sessions after considering previous studies describing a variable number of treatments, ranging from 3 to 5, for shoulder pain in rotator cuff tendinopathy.[37] Each participant received 700 pulses of shockwaves per session, focused on the localized area of the supraspinatus tendon insertion. All therapy was carried out without anesthesia. Subjects in the first group received focused ESWT alone. Ten days after the last focused ESWT, subjects in the second group received 10 additional sessions of IE, 3 times per

TABLE 2 Within- and Between-Group Differences of All Outcome Measures of Participants Who Received Focused ESWT Alone and Focused ESWT Plus IE

Measure	Baseline	10 d Posttreatment	2 mo Posttreatment	*P* Value
Outcomes*				
VAS				
ESWT	8.1 ± 0.6	5.1 ± 0.9	3.4 ± 0.8	<.001
ESWT plus IE	8.2 ± 0.8	4.9 ± 1.3	1.5 ± 0.5	<.001
P value		>.05	<.001	
CMS				
ESWT	49.7 ± 7.9	65.1 ± 7.7	75.9 ± 6.7	<.001
ESWT plus IE	45.6 ± 9.8	63.6 ± 8.7	92.1 ± 6.3	<.001
P value		>.05	<.001	
Within-group change score from baseline†				
VAS				
ESWT		–3.0 (–3.6, –2.5)	–4.7 (–5.3, –4.2)	
ESWT plus IE		–3.3 (–4.0, –2.6)	–6.7 (–7.2, –6.2)	
CMS				
ESWT		15.4 (12.5, 18.2)	26.2 (23.2, 29.2)	
ESWT plus IE		18.0 (14.7, 21.3)	46.5 (41.9, 51.2)	
Between-group difference in change score†				
VAS		–0.2 (–0.8, 0.4)	–1.9 (–2.5, –1.4)	
CMS		–1.5 (–5.4, 2.5)	16.2 (12.6, 19.8)	

Abbreviations: CMS, Constant-Murley score; ESWT, extracorporeal shockwave therapy; IE, isokinetic exercise; VAS, visual analog scale.
**Values are mean ± SD unless otherwise indicated.*
†Values are mean difference (95% confidence interval) unless otherwise indicated.

week. We chose this time interval before starting with IE, given the possible pain increase during ESWT. Each subject was positioned for eccentric/concentric shoulder internal/external rotation in 45° of shoulder abduction, 30° of flexion, and the elbow in 90° of flexion.[21] The training protocol consisted of 3 sets of 10 repetitions during the first week at the concentric and eccentric speeds of 240°/s and 180°/s. During the second week, training was progressed to 4 sets of 10 repetitions. In the last week, the concentric speed was decreased to 120°/s, while the eccentric speed was decreased to 90°/s.[34] Furthermore, in this final week of training, the participants received 5 repetitions of isometric training at 30°/s of external rotation. We used training speeds reported in previous studies.[34] The rationale for decreasing speeds over time in the training program is that low speeds can stress rotator cuff tendons during the performances, so the progressive increase of training enhances rotator cuff muscle strength. Subjects were assessed at baseline (before the first treatment session), 10 days after the last treatment session with focused ESWT, and 2 months after the last session with focused ESWT. The ethical committee stipulated that all participants could receive other interventions that were not part of the research protocol of the present study in case of failure after 2 months. After 6 months from baseline, a phone interview with all subjects treated was made to assess clinical improvements and, in case of insufficient treatment success, to allow for other physical therapy interventions. Therefore, our purpose was to examine the effectiveness of isokinetics for improving power output with isokinetic shoulder measurements in order to establish shoulder strength values and balance ratios (conventional and functional) that can be employed in preventive, training, and rehabilitation strategies for shoulder injuries. Participants received no other physical therapy intervention for shoulder pain during the study and 4 to 5 weeks prior to the study. The subjects were instructed to avoid analgesic/anti-inflammatory drugs for the duration of the physical therapy period and to abstain from the execution of painful activities of daily living involving the affected shoulder.

Statistical Analysis

To assess the distribution of the variables, we used the Bartlett test. The data for explored variables (ie, VAS and CMS scores) and isokinetic data (peak torque, total work) at 210°/s, 180°/s, and 120°/s were analyzed using separate 2-by-3 (group-by-time) mixed-model analyses of variance (P values less than .05 were significant). With regard to the isokinetic variables, the variables analyzed were difference between mean values of peak torque and total work between affected and unaffected side. For power analysis and sample-size estimation, G*Power Version 3.1.10 software (Heinrich-Heine Universität, Düsseldorf, Germany) was used. Data analyses were performed using Stata/MP Version 10.1 (StataCorp LP, College Station, TX). Our sample of 15 patients in each group provided a power greater than 80% to detect a difference of 3.5 points on the VAS between the 2 measurements, assessing an SD of 1, correlation of 0.7, and alpha of .05.

RESULTS

A total of 45 consecutive outpatients (25 women and 20 men) were screened for study eligibility. At the end of the evaluation, 30 individuals with SAIS who fulfilled the selection criteria and agreed to participate were enrolled in the study (16 women, 14 men; mean ± SD age, 40.2 ± 5.0 years). Written informed consent was obtained from all subjects. Reasons for exclusion are shown in a flow diagram of subject recruitment and retention (**FIGURE**). Enrolled participants were randomly assigned to 1 of 2 groups: 15 subjects (9 women, 6 men; mean ± SD age, 39.4 ± 3.9 years) who received focused ESWT alone, and 15 individuals (7 women, 8 men; mean ± SD age, 41.1 ± 6 years) who received focused ESWT plus IE. All 30 participants completed the trial and were included in the analysis (**TABLE 1**). None of the participants reported adverse effects or reported taking analgesic/anti-inflammatory drugs during the period of their participation in the study. There was a statistically significant group-by-time interaction for the 2-by-3 mixed-model analyses of variance for VAS and CMS scores, and for all isokinetic data (peak torque and total work at 210°/s, 180°/s, and 120°/s) (P<.05). In those who received focused ESWT and focused ESWT plus IE, a statistically significant decrease (P<.05) in VAS pain scores and a statistically significant increase (P<.05) in CMS scores were found 10 days after the last treatment session with focused ESWT and after 2 months of follow-up (**TABLE 2**). The VAS score reduction was statistically greater in the focused ESWT–plus-IE group (mean score, 1.5 ± 0.5) in comparison with the focused-ESWT group (mean score, 3.4 ± 0.8) after 2 months of follow-up. Moreover, the CMS score was statistically greater in the focused ESWT–plus-IE group (mean, 92.1 ± 6.3) than in the focused-ESWT group (mean, 75.9 ± 6.7) after 2 months of follow-up (**TABLE 2**).

For isokinetic test data, considering the differences between affected and unaffected shoulders evaluated at baseline for patients of both groups, the positive effects of this treatment on rotator cuff tendons were associated with a statistically significant reduction (P<.05) in affected versus unaffected shoulders for peak torque and total work output at 210°/s, 180°/s, and 120°/s 10 days after the last treatment session with ESWT and after the 2-month follow-up (**TABLE 3**). After the treatment, isokinetic test data for subjects receiving ESWT alone for the affected shoulder showed a

TABLE 3 Changes in Peak Torque and Total Work Difference for External Rotation Between Affected and Unaffected Shoulders in Participants With Subacromial Impingement Syndrome in the Group With Focused ESWT Alone and in the Group With Focused ESWT Plus IE

Measure	Baseline	10 d Posttreatment	2 mo Posttreatment	*P* Value
Outcomes*				
External rotation at 210°/s				
Peak torque, Nm/kg body weight				
ESWT	40.9 ± 20.7	21.8 ± 10.6	17.9 ± 7.9	<.001
ESWT plus IE	38.9 ± 25.9	21.3 ± 13.3	9.7 ± 6.9	<.001
Total work, J/kg body weight				
ESWT	56.2 ± 17.5	41.7 ± 13.7	35.5 ± 12.1	<.01
ESWT plus IE	51 ± 19.1	42.8 ± 19.2	21.5 ± 16.1	<.001
External rotation at 180°/s				
Peak torque, Nm/kg body weight				
ESWT	46.7 ± 12.7	40.1 ± 11.7	31.0 ± 8.4	<.01
ESWT plus IE	43.6 ± 13.4	27.3 ± 14.7	14.6 ± 13.6	<.001
Total work, J/kg body weight				
ESWT	47.1 ± 18.5	38.8 ± 19.1	28.0 ± 4.3	<.05
ESWT plus IE	44.7 ± 22.5	36.9 ± 21.1	15.5 ± 11.9	<.001
External rotation at 120°/s				
Peak torque, Nm/kg body weight				
ESWT	41.3 ± 10.1	28 ± 7.3	23.9 ± 8	<.001
ESWT plus IE	39.2 ± 14	22.5 ± 11.6	9.9 ± 9.2	<.001
Total work, J/kg body weight				
ESWT	57.8 ± 10.1	42.3 ± 14.2	34 ± 10.4	<.001
ESWT plus IE	51.5 ± 12.5	44.3 ± 18.1	27.7 ± 12.8	<.001
Within-group change score from baseline†				
External rotation at 210°/s				
Peak torque, Nm/kg body weight				
ESWT		–19.2 (–27.5, –10.7)	–23.0 (–32.0, –13.9)	
ESWT plus IE		–17.6 (–29.6, –5.6)	–29.1 (–42.8, –15.4)	
Total work, J/kg body weight				
ESWT		–14.5 (–18.0, –10.9)	–20.7 (–25.3, –16.1)	
ESWT plus IE		–8.2 (–18.4, 2.1)	–29.5 (–44.5, –14.5)	
External rotation at 180°/s				
Peak torque, Nm/kg body weight				
ESWT		–6.6 (–8.8, –4.4)	–15.7 (–18.7, –11.8)	
ESWT plus IE		–16.3 (–23.8, –8.7)	–29.0 (–37.4, –20.6)	
Total work, J/kg body weight				
ESWT		–8.3 (–12.8, –3.8)	–19.1 (–25.2, –13.1)	
ESWT plus IE		–7.8 (–17.1, 1.5)	–29.2 (–38.9, –19.5)	

Table continues on page 720.

statistically significant increase (P<.05) in mean values for external rotation peak torque at 210°/s and total work output at 210°/s, 180°/s, and 120°/s 10 days after the last treatment session with ESWT and after 2 months of follow-up (**TABLE 4**). Subjects who received both ESWT and IE showed a statistically significant increase (P<.05) in mean external rotation peak torque and total work output at 210°/s, 180°/s, and 120°/s 10 days after the last treatment session with ESWT and after 2 months of follow-up (**TABLE 4**).

Moreover, the effectiveness of IE for muscle functional recovery can be demonstrated considering isokinetic test data differences between both shoulders in both groups. The observed differences between affected and unaffected shoulders in peak torque at 180°/s were significantly reduced 10 days after the last treatment session with ESWT (P<.05) and after 2 months of follow-up (P<.001), while at 120°/s and 210°/s, peak torque was significantly reduced only after 2 months of follow-up (P<.001 and P<.01, respectively) in subjects in the focused ESWT–plus-IE group compared to subjects in the focused-ESWT group. In terms of total work output, these differences were statistically reduced only after 2 months of follow-up at 210°/s (P<.05) and 180°/s (P<.05) in subjects in the focused ESWT–plus-IE group compared to subjects in the focused-ESWT group. Finally, after the 2-month follow-up, there was a statistically significant increase in total work output at 210°/s (P<.05), 180°/s (P<.05), and 120°/s (P<.001) in subjects in the focused ESWT–plus-IE group compared to subjects in the focused-ESWT group.

During phone interviews 6 months after baseline, 9 subjects in the focused-ESWT group (60%) and 11 subjects in the focused ESWT–plus-IE group (73.3%) referred to having an improvement of their clinical picture (P<.05). Five participants in the focused-ESWT group (33.3%) and 4 in the focused ESWT–plus-IE group (26.7%) reported worsened pain (P<.05) and underwent another type of physical therapy. Only 1 subject in the focused-ESWT group (6.7%) submitted to surgery.

TABLE 3 Changes in Peak Torque and Total Work Difference for External Rotation Between Affected and Unaffected Shoulders in Participants With Subacromial Impingement Syndrome in the Group With Focused ESWT Alone and in the Group With Focused ESWT Plus IE (continued)

Measure	Baseline	10 d Posttreatment	2 mo Posttreatment	*P* Value
Within-group change score from baseline† (continued)				
External rotation at 120°/s				
Peak torque, Nm/kg body weight				
ESWT		–13.3 (–16.1, –10.6)	–17.4 (–29.9, –13.8)	
ESWT plus IE		–16.7 (–20.2, –13.3)	–29.3 (–35.5, –23.0)	
Total work, J/kg body weight				
ESWT		–15.5 (–19.5, –11.4)	–23.8 (–26.8, –20.7)	
ESWT plus IE		–7.2 (–15.8, 1.4)	–23.8 (–31.5, –16.3)	
Between-group difference in change score†				
External rotation at 210°/s				
Peak torque, Nm/kg body weight		–0.5 (–4.2, 3.2)	–8.2 (–10.9, –5.4)	
Total work, J/kg body weight		1.1 (–5.7, 7.8)	–14.0 (–23.3, –4.7)	
External rotation at 180°/s				
Peak torque, Nm/kg body weight		–12.8 (–22.2, –3.4)	–16.4 (–23.6, –10.1)	
Total work, J/kg body weight		–1.9 (–8.9, 5.1)	–12.5 (–20.4, –4.7)	
External rotation at 120°/s				
Peak torque, Nm/kg body weight		–5.5 (–9.3, –1.7)	–14.0 (–18.5, –9.4)	
Total work, J/kg body weight		2.0 (–3.9, 7.9)	–6.3 (–9.7, –2.9)	

Abbreviations: ESWT, extracorporeal shockwave therapy; IE, isokinetic exercise.
**Values are mean ± SD unless otherwise indicated.*
†Values are mean difference (95% confidence interval) unless otherwise indicated.

DISCUSSION

In the present study, individuals with SAIS who received a combined intervention of focused ESWT plus IE reported reduced pain and showed successful functional recovery in the short to medium term. To date, no studies have tested the possible benefits of ESWT and IE for SAIS. Among physical modalities, ESWT represents an important treatment for a number of musculoskeletal conditions, including tendinopathies and enthesopathies.[30,73] On the other hand, several studies have emphasized the positive effect of both focused and radial ESWT for the treatment of chronic calcific tendinitis of the shoulder.[7,12,25,28,30,33,36,49,51,63,66,67,81] There is, however, less evidence to support the effectiveness of ESWT for SAIS without calcification.[30,49,76,81] In the present study, following ESWT, participants in both groups reported a statistically significant improvement in the overall clinical picture as assessed by the VAS and CMS for pain and isokinetic testing. The first important result was the effectiveness of ESWT in the treatment of pain, functionality, and muscle weakness resulting from SAIS. When the ESWT was combined with IE, the subjects showed a statistically significant greater reduction in pain and improvements in articular movement, functionality, and muscle endur-

TABLE 4 Within-Group Differences for the Affected Shoulder of Patients With Subacromial Impingement Syndrome in the Group With Focused ESWT Alone and in the Group With Focused ESWT Plus IE in Isokinetic Testing Data for External Rotation at 210°/s, 180°/s, and 120°/s

Measures	Baseline	10 d Posttreatment	2 mo Posttreatment	*P* Value
Outcomes*				
External rotation at 210°/s				
Peak torque, Nm/kg body weight				
ESWT	13.9 ± 4.7	14.8 ± 4.4	16.9 ± 3.2	<.05
ESWT plus IE	12.8 ± 2.9	12.8 ± 2.9	16.5 ± 3.3	<.05
Total work, J/kg body weight				
ESWT	17.7 ± 8.7	23.1 ± 9.7	33.8 ± 9.6	<.001
ESWT plus IE	20.0 ± 16.1	28.1 ± 16.8	53.9 ± 27.3	<.001
External rotation at 180°/s				
Peak torque, Nm/kg body weight				
ESWT	13.4 ± 2.8	14.3 ± 2.9	16.9 ± 3.9	>.05
ESWT plus IE	12.0 ± 2.8	13.4 ± 2.8	17.5 ± 7.1	<.01
Total work, J/kg body weight				
ESWT	18.6 ± 10.8	23.9 ± 11.2	34.7 ± 13.5	<.01
ESWT plus IE	22.9 ± 19.0	31.9 ± 18.1	62.4 ± 30.8	<.001
External rotation at 120°/s				
Peak torque, Nm/kg body weight				
ESWT	12.6 ± 4.1	14.3 ± 5.1	17 ± 5.9	>.05
ESWT plus IE	11.3 ± 2.5	12.5 ± 3.8	17.9 ± 9.1	<.01
Total work, J/kg body weight				
ESWT	18.9 ± 7.3	23.8 ± 8.2	34.3 ± 8.7	<.001
ESWT plus IE	22.8 ± 12.9	26.3 ± 13.1	52.6 ± 16.2	<.001
Within-group change score from baseline†				
External rotation at 210°/s				
Peak torque, Nm/kg body weight				
ESWT		0.9 (0.01, 1.8)	3.0 (1.1, 4.9)	
ESWT plus IE		0.0 (–1.2, 1.2)	3.7 (2.3, 5.0)	
Total work, J/kg body weight				
ESWT		5.4 (3.6, 7.2)	16.1 (13.5, 18.6)	
ESWT plus IE		8.1 (4.1, 11.9)	33.9 (23.4, 44.3)	
External rotation at 180°/s				
Peak torque, Nm/kg body weight				
ESWT		0.9 (0.08, 1.8)	3.5 (1.5, 5.6)	
ESWT plus IE		1.4 (0.2, 2.7)	5.5 (2.4, 8.6)	
Total work, J/kg body weight				
ESWT		5.3 (3.2, 7.5)	16.1 (11.4, 20.7)	
ESWT plus IE		9.0 (2.8, 15.2)	39.5 (27.0, 52.1)	

Table continues on page 722.

ance of the affected shoulder compared with those treated only with ESWT. The contrasting findings of ESWT alone for SAIS could be explained by the multifactorial pathoetiology of this syndrome, caused not only by the degenerative process of tendons but also by abnormal scapular and humeral kinematics, postural abnormalities, rotator cuff and scapular muscle performance deficits, and decreased extensibility of pectoralis minor or posterior shoulder tissues.[29] Treatment of patients with impingement symptoms commonly includes exercises intended to restore "normal" movement patterns.

Based on these concepts, a combined treatment of ESWT and IE for rehabilitation of SAIS may be an effective treatment protocol. Isokinetic exercise is useful in the treatment of shoulder dysfunction to increase the muscle's endurance and torque, reducing the involuntary hyperactivity of rotator cuff muscles responsible for weakness and pain during shoulder movements.[17,34] Therefore, the isokinetic test may play an important part in the measurement of muscular performance before and after a rehabilitative treatment. The objective documentation that the isokinetic test provides allows clinicians and researchers to report muscle torque, power, work, and endurance as important outcome measures of an evidence-based rehabilitation program after injury.[17,50] The subjects enrolled in the present study received concentric external rotation exercises for the affected shoulder because eccentric contraction induces significant engagement of the supraspinatus muscle tendon, which had just been challenged by ESWT. Furthermore, the supraspinatus and infraspinatus components of the rotator cuff contribute to a variable proportion of the total torque of abduction (25%-50%) and external rotation (50%-75%) throughout the ROM, so the external rotation work helps to train these muscles predominantly.[46] In fact, the purpose of IE is to increase muscle endurance. It is known that SAIS is not restricted to overuse activities, and also involves weakness and shoulder muscle impairment. Therefore, any improvement in total work, a parameter of muscle endurance, can be considered more useful than peak torque in reducing the risk

TABLE 4 Within-Group Differences for the Affected Shoulder of Patients With Subacromial Impingement Syndrome in the Group With Focused ESWT Alone and in the Group With Focused ESWT Plus IE in Isokinetic Testing Data for External Rotation at 210°/s, 180°/s, and 120°/s (continued)

Measure	Baseline	10 d Posttreatment	2 mo Posttreatment	*P* Value
Within-group change score from baseline† (continued)				
External rotation at 120°/s				
Peak torque, Nm/kg body weight				
ESWT		1.7 (0.5, 2.8)	4.4 (2.7, 6.1)	
ESWT plus IE		1.2 (0.03, 2.4)	6.6 (2.2, 10.9)	
Total work, J/kg body weight				
ESWT		4.8 (3.2, 6.4)	15.4 (12.0, 18.8)	
ESWT plus IE		3.5 (0.9, 6.1)	29.8 (21.7, 37.8)	
Between-group difference in change score†				
External rotation at 210°/s				
Peak torque, Nm/kg body weight		–2.0 (–5.0, 1.0)	–0.4 (–2.8, 2.0)	
Total work, J/kg body weight		5.0 (–2.3, 12.2)	20.1 (7.9, 32.2)	
External rotation at 180°/s				
Peak torque, Nm/kg body weight		–0.9 (–2.9, 1.1)	–0.6 (–2.1, 3.2)	
Total work, J/kg body weight		8.0 (0.4, 15.4)	27.7 (13.3, 42.1)	
External rotation at 120°/s				
Peak torque, Nm/kg body weight		–1.8 (–3.5, –0.9)	0.9 (–1.9, 3.6)	
Total work, J/kg body weight		2.5 (–2.3, 7.3)	18.3 (11.4, 25.3)	

Abbreviations: ESWT, extracorporeal shockwave therapy; IE, isokinetic exercise.
**Values are mean ± SD unless otherwise indicated.*
†Values are mean difference (95% confidence interval) unless otherwise indicated.

of recurrence of painful shoulder tendinitis. After ESWT, some studies suggested the efficacy of eccentric exercises for the treatment of Achilles tendinopathy and jumper's knee,[43,68,69] confirming the present findings on SAIS. Moreover, evidence from a recent randomized controlled trial indicated that supervised exercises were more effective than radial ESWT for the treatment of subacromial shoulder pain in the short to medium term.[16] No significant difference was found between supervised exercises and radial ESWT at 1 year of follow-up.[18] These findings confirmed the rationale of the present study of adding IE to ESWT in the treatment of SAIS.

The improvements in the VAS, CMS, and isokinetic data could be explained by the positive metabolic effect of ESWT on tendons and pain.[54,82] Wang and colleagues[83] also stated that ESWT caused tissue healing, whereas other authors have hypothesized that increases in transforming growth factor β1 and insulin-like growth factor 1 expression may mediate mitogenic and anabolic responses of tendon tissue and tenocytes, as well as neovascularization, that contribute to the success of ESWT in resolving tendinitis.[8,36] Tendon healing and pain reduction induce the recovery of rotator cuff muscle strength. However, participants receiving additional IE showed a statistically significant increase in the mean value of external rotation peak torque at 210°/s and total work output of 5 repetitions at 210°/s, 180°/s, and120°/s after 2 months of follow-up compared with participants receiving focused ESWT alone. We also noted a statistically significant improvement of external rotation peak torque only at 210°/s, suggesting that at the end of ESWT, shoulder pain may still be present and thus may interfere with IE at slow velocity (external rotation at 180°/s and 120°/s). Total work of 5 repetitions at 210°/s, 180°/s, and 120°/s in the focused ESWT–plus-IE group was higher than in the focused-ESWT group because it is related to major endurance after IE. The positive effect of ESWT and ESWT combined with IE was evaluated when comparing differences in isokinetic data between both shoulders of participants in both groups. Peak torque and total work of 5 repetitions at 210°/s, 180°/s, and 120°/s showed a statistically significant improvement 10 days after ESWT and after 2 months of follow-up. This may be related to the positive effect of ESWT on tendons, to restore rotator cuff function and strength. This effect was more evident for the focused ESWT–plus-IE group than for the focused-ESWT group at external rotation at 210°/s and 180°/s, whereas the differences in isokinetic values between unaffected and affected shoulders in both groups were not statistically significant at external rotation at 120°/s. This may be due to difficulties for patients at slow velocities.

The present study showed promising treatment effects during rehabilitation of SAIS. Further clinical studies are needed to verify the effects over a longer follow-up and in terms of reducing any recurrence of problems. Limitations of this study include the lack of a placebo or sham control group that received no treatment whatsoever, which restricts our ability to claim cause and effect. Results from 1 trial reporting no difference between sham therapy and ESWT in noncalcific tendinitis of the rotator cuff suggest that a sham group should have been included.[76] Another limitation is the lack of longer follow-up data, which reduces the clinical application of our findings to long-term SAIS treatment. The sample size was also small, although it yielded statistically significant results, which now need to be replicated in larger samples over longer follow-up periods. Furthermore, the absence of radiographic imaging or MRI, which is useful to evaluate anatomical structures of the rotator cuff at follow-up, may be a potential limitation. Notwithstanding the good psychometric properties of the 2 measurement tools used in the present study, we only have MCID data on the VAS, limiting our ability to attribute clinical significance to the differences between groups observed on the CMS. However, the difference in the change in the VAS scores between groups (1.9 points) surpassed the MCID for this tool.[14] On the other hand, the 95% confidence interval of the SEM for the CMS was ±17.7 points,[10] and the between-group difference did not surpass the SEM (16.2 points). Finally, an important and valuable aspect of this trial is the safety of this treatment. In fact, no patients interrupted ESWT for pain relief, and IE was well tolerated and performed.

CONCLUSION

In conclusion, in the treatment of SAIS, ESWT combined with IE reduced pain and improved functionality and muscle endurance of the affected shoulder. In the attempt to explain the mechanisms underlying the effectiveness of this combined treatment for SAIS, we speculated that ESWT may induce a metabolic stimulation of tendon tissue, whereas IE may improve scapulo-humeral kinematics and reduce rotator cuff and scapular muscle performance deficits resulting from SAIS. We therefore proposed the potential value of providing IE after ESWT to improve patient outcomes for treatment of SAIS rather than using ESWT alone. ◉

KEY POINTS

FINDINGS: In patients with SAIS, combined administration of focused ESWT and IE for the rotator cuff resulted in greater reduction in pain, as well as superior functional recovery and muscle endurance of the affected shoulder, in the short to medium term compared to ESWT alone.

IMPLICATIONS: In SAIS, IE after ESWT appears to improve patient outcomes more than ESWT alone.

CAUTION: The lack of a placebo control group, the lack of a longer follow-up period, and the small sample size were limitations of the present study.

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