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Original Article

Low-level laser therapy versus ultrasound therapy combined with home-based exercise in patients with subacromial impingement syndrome: A randomized-controlled trial

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ABSTRACT

Objectives: The aim of this study was to evaluate the effects of low-level laser therapy (LLLT) and therapeutic ultrasound (US) combined with home-based exercise (HBE) versus HBE alone in patients with subacromial impingement syndrome (SAIS).

Patients and methods: Between March 2021 and July 2021, a total of 60 patients with SAIS (19 males, 41 females; mean age: 51.3±10.4 years; range, 30 to 70 years) were included. The patients were randomly allocated to an LLLT group (LG), an US therapy group (UG), and a control group (CG). The LLLT and US therapy programs were applied five times a week, for a total of 15 sessions. Home-based exercise programs and cold-pack therapy were administered to patients in each group. The patients were evaluated at baseline and one and three months of follow-up using the Visual Analog Scale (VAS) for pain during activity, at rest, and at night, and the Shoulder Pain and Disability Index (SPADI).

Results: All groups showed a significant improvement in the VAS and SPADI scores after the first month ($p<0.05$). The VAS activity pain score ($p=0.008$), SPADI pain score ($p=0.003$), SPADI disability score ($p=0.012$), and SPADI total score ($p=0.003$) significantly decreased in the LG compared to the CG at one month of follow-up. However, there were no significant differences in the outcome measures among the three groups at three months ($p>0.05$).

Conclusion: The LLLT combined with HBE is more effective than HBE program alone for relieving activity pain and improving shoulder functions in the short term. However, LLLT and US therapy do not provide additional effects in terms of pain and disability at three months.

Keywords: Exercise, laser therapy, pain, shoulder, therapeutic ultrasound.

Shoulder pain is a common musculoskeletal condition in the general population and subacromial pain is one of the common underlying diagnoses.[1,2] Possible causes of shoulder pain related to subacromial impingement syndrome (SAIS) include various intrinsic and extrinsic factors.[3,4] However, the description of SAIS can be challenging due to the lesions varying from rotator cuff tears to subacromial bursitis.[5]

Subacromial impingement syndrome is a significant cause of pain and impairment that interferes with daily living activities. Therefore, one of the primary goals of SAIS therapy is to alleviate pain and enhance upper extremity function.[6] Non-operative management of SAIS includes pain medication, exercise, physical therapy, and injections.[7] Low-level laser therapy (LLLT) and therapeutic ultrasound (US) are widely employed for the treatment of painful musculoskeletal disorders, including tendinopathy and SAIS.[8-10]

A systematic review investigating the efficacy of electrotherapy modalities in patients with rotator

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cuff disease found that therapeutic US and LLLT may provide benefits compared to placebo in the short term.[10] Additionally, the results of another systematic review revealed that LLLT was more effective than placebo or US for subacromial impingement syndrome.[11] However, a recent update of the systematic reviews examining the efficacy of physical therapy modalities reported that the evidence did not support the effectiveness of laser therapy and therapeutic US as a monotherapy for subacromial shoulder pain.[12] However, a limited number of randomized-controlled studies compared the effects of LLLT and therapeutic US on clinical outcomes in patients with SAIS.[13,14] Therefore, the data on the effects of LLLT and therapeutic US on SAIS seem to be controversial. Moreover, exercise is widely regarded as an effective intervention for symptomatic rotator cuff tendinopathy.[15] Additionally, a systematic review and meta-analysis concluded that combined treatment composed of exercise and other therapies might have better effects than single-intervention therapies in the management of rotator cuff tendinopathy.[16]

In the light of these data, in the present study, we aimed to assess whether LLLT and US therapy combined with a home-based exercise (HBE) program were superior over each other and to evaluate their effectiveness in patients with SAIS versus an HBE regimen alone.

PATIENTS AND METHODS

This single-center, single-blind, prospective, randomized-controlled interventional study was conducted at Istanbul University Istanbul Faculty of Medicine, Department of Physical Medicine and Rehabilitation between March 2021 and July 2021. A total of 110 consecutive patients with shoulder pain were screened. Among these patients, a total of 60 with SAIS (19 males, 41 females; mean age: 51.3±10.4 years; range, 30 to 70 years) who met the eligibility criteria were included in the study. The diagnosis of SAIS was based on physical examinations and was confirmed by a radiologist using magnetic resonance imaging (MRI) within the past three months of enrollment. The Zlatkin's MRI staging was used to assess the pathological findings in the rotator cuff tendons to confirm the diagnosis.[17] Only patients with Stage 2 were included. Stage 2 was defined as a tendon with both abnormal signal intensity and morphology (obvious tendon thinning or irregularity).[17]

At least one positive outcome of the Hawkins-Kennedy impingement test, Neer impingement test, or painful-arc test was required for physical examination qualification. Additional inclusion criteria were as follows: adults over 30 years of age; at least two months of persistent pain in one shoulder; no passive restrictions on shoulder range of motion (ROM); and failure of improvement in pain after oral and/or topical analgesic medications. Exclusion criteria included a history of malignancy and systemic rheumatic diseases; evidence of systemic or local infection; the presence of major trauma at the affected shoulder; any intraarticular or subacromial shoulder injection within the past three months; history of physical therapy for at least six months prior to the study; history of shoulder surgery; rotator cuff lesions confirmed by MRI as either calcific tendinosis or a full-thickness tear; diabetes mellitus; and comorbidity severe enough to affect participation in the study protocol.

Randomization and interventions

Eligible participants were randomly assigned to one of the three groups by an independent blinded researcher using computer-generated random numbers and an allocation ratio of 1:1:1: the LLLT group (LG, n=20), the US therapy group (UG, n=20), and the control group (CG, n=20). The outcome assessor and principal investigator were blinded to the group allocation. The LLLT and US therapy programs were applied five times a week, once a day for a total of 15 sessions by the same experienced physiotherapist. All participants performed an HBE program and received cold-pack therapy applied for 10 min.

The LG received treatment with a gallium-aluminum-arsenide diode laser device (Chattanooga Medical Supply Inc., TN, USA), a wavelength of 850 nm, a power output of 100 mV, and a continuous wave at five points over the shoulder. The LLLT was applied with a dose of 3 Joule/cm^2 over the greater and lesser tubercles, the bicipital groove, and the anterior and posterior aspects of the capsule for 1 min at each point. The duration of laser treatment was 5 min for each patient. In the LG, each patient received LLLT and cold-pack therapy and performed an HBE program. The UG received treatment using a therapeutic US machine (Chattanooga Medical Supply Inc., TN, USA) with a transducer head size of 5 cm^2. Pulsed US was applied with a frequency of 1 MHz and a power of 1.0 W/cm^2 for 5 min. In the UG, each patient received US therapy, and cold-pack therapy and performed an HBE program. In the CG, patients performed the HBE program and received cold-pack therapy.

The HBE program included posture, pectorals and trapezius stretching exercises, shoulder ROM exercises, gentle shoulder stretching exercises, Codman's pendulum exercises, and finger stair exercise. After the patients achieved an active full ROM, they performed strengthening exercises for the rotator cuff and scapular muscles. Initially, the patients were advised to perform the HBE three days per week; each exercise consists of one set of five repetitions. The exercise intensity was gradually raised by increasing the number of exercise sessions and the number of series for each exercise. The HBE program was followed five times a week, once a day with 10 to 15 repetitions over four weeks. All three groups participated in the same HBE program.

The same researcher gave instructions on how to perform the exercises to each participant before the study began. During weekly telephone conversations with all participants, exercise compliance was encouraged and evaluated. All individuals were discouraged from beginning new therapies for their shoulder pain and using non-steroidal anti-inflammatory medications throughout the study. Acetaminophen was recommended to the individuals as required. Figure 1 shows the suggested Consolidated Standards of Reporting Trials (CONSORT) flow diagram for randomized-controlled trials, along with the causes of dropouts/withdrawals in the randomized groups.

Outcome measures

The sociodemographic characteristics of the patients and the duration of shoulder pain were recorded. All patients underwent physical examinations, and the ROM of the shoulder (flexion, abduction, internal rotation, and external rotation) was measured by goniometry. The severity of rest pain, activity pain, and nocturnal pain were evaluated using the Visual Analog Scale (VAS); shoulder pain and disability were assessed using the Shoulder Pain and Disability Index (SPADI) at baseline, one month, and three months. The primary outcome of the study was VAS activity pain, and all other outcome measures were considered secondary. All evaluations were conducted by a single researcher who was blinded to the treatment allocation.

The VAS is used to measure the average rest, activity, and nocturnal pain levels at the affected shoulder throughout the preceding week, with scores ranging from 0 to 10.[18,19] The SPADI consists of 13 items: five measure shoulder pain and eight measure shoulder disability.[20] The score is transformed to a 100-point scale, where a higher score indicates a worsening status. The SPADI is a reliable and highly responsive tool for evaluating shoulder pain and function.[21,22]

Statistical analysis

The sample size was calculated prior to the study using the predicted differences and standard deviations (SDs) from previous studies assessing the effect of LLLT in patients with shoulder pain. A sample size of 20 patients in each group was required, assuming a dropout rate of 10% and a power of 80% at a significance level of 5% to identify a minimum difference of about three points in VAS compared to baseline.[23,24]

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. The Shapiro-Wilk test was used to assess the normality of the distribution. Non-parametric tests were performed, since none of the variables showed a normal distribution. Intra-group comparisons were performed using the Friedman and Wilcoxon signed-rank tests. The Kruskal-Wallis test was used to compare the difference between the groups and the Mann-Whitney U test was used to analyze pair-wise comparisons. The significance level for the multiple comparison test was calculated as 0.017 using the Bonferroni correction. The dropout participants were excluded from the final analysis, since the per-protocol analysis was carried out. A p value of <0.05 was considered statistically significant.

RESULTS

There was no significant difference between the dropout patients regarding demographic/clinical parameters and outcome measures. As shown in Table 1, there were no significant differences among the three groups in terms of baseline clinical characteristics and physical examination findings ($p>0.05$). Compliance with the HBE program was expressed in percentage of each participant's attendance at prescribed sessions. Accordingly, compliance with the HBE was 80.5% for the UG, 79.5% for the LG, and 77% for the CG. There was no significant difference in compliance rates among the groups ($p>0.05$).

The baseline VAS pain and SPADI scores were similar ($p>0.05$) among the three groups (Table 2).

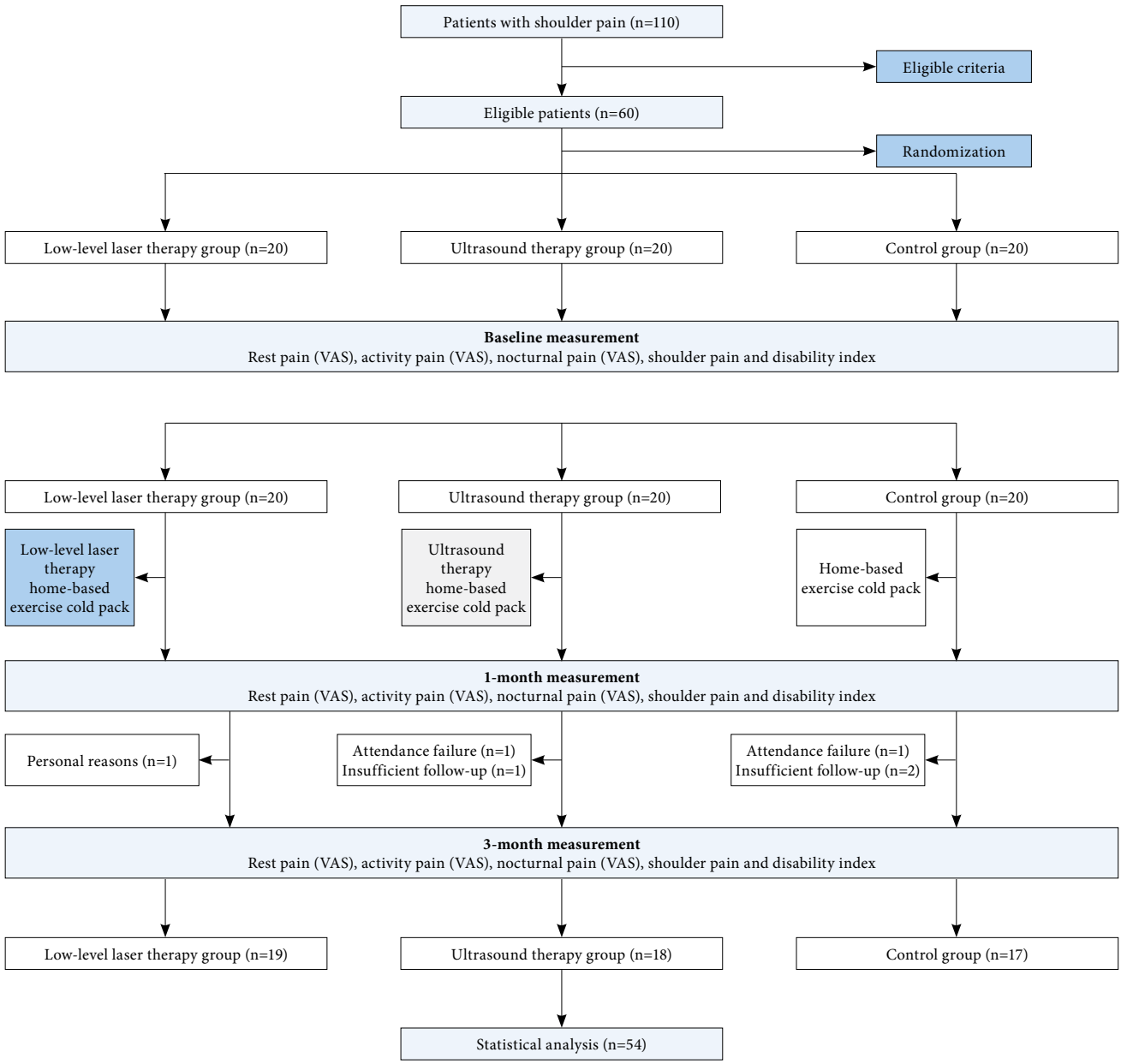

Figure 1. Study flowchart.
VAS: Visual Analog Scale.

However, intra-group analysis showed that the VAS activity pain, VAS nocturnal pain, and SPADI scores significantly decreased in all three groups at one month ($p<0.05$). Both the LG and UG showed significant reductions in all outcome measures throughout three months ($p<0.05$). There was also a significant improvement in the CG in terms of VAS activity pain, VAS nocturnal pain, and SPADI pain scores at three months of follow-up.

The VAS activity pain and SPADI pain scores significantly decreased at one month in the LG compared to the CG ($p=0.008$ and $p<0.003$, respectively). Similarly, SPADI disability (-17.4%, $p<0.012$) and SPADI total (-31.8%, $p=0.003$) scores showed a greater improvement in the LG than in the CG at the end of the three months using a *p* value of 0.017. However, the pairwise comparison did not reveal a significant difference among the

TABLE 1
Demographic and clinical characteristics of patients

	LG (n=19)					UG (n=18)					CG (n=17)					
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	*p*
Age (year)			52.2 ± 8.3	54.0	30-66			48.5 ± 11.9	46.0	32-70			54.7 ± 10.7	54.0	30-70	0.121†
Duration of symptoms (month)			9.1 ± 8.4	6.0	2-24			6.2 ± 6.1	4.0	2-24			8.3 ± 7.1	6.0	2-24	0.677†
Shoulder ROM-active flexion (degree)			177.8 ± 6.3	180	160-180			178.3 ± 5.1	180	160-180)			180.0 ± 0.0	180	180-180	0.378†
Abduction (degree)			178.9 ± 4.5	180	160-180			180.0 ± 0.0	180	180-180			178.8 ± 4.8	180	160-180	0.598†
Internal rotation (degree)			86.8 ± 7.4	90.0	70-90			88.3 ± 5.1	90.0	70-90			85.8 ± 7.1	90.0	70-90	0.416†
External rotation (degree)			88.9 ± 4.5	90.0	70-90			89.4 ± 2.3	90.0	80-90			89.4 ± 2.4	90.0	80-90	0.999†
Sex																0.238‡
Female	15	78.9				10	55.6				13	76.5				
Male	4	21.1				8	44.4				4	23.5				
Job																0.648‡
Housewife or retired	10	52.6				9	50.0				11	64.7				
Active employe	9	47.4				9	50.0				6	35.3				
Affected shoulder																0.087‡
Right	11	57.9				14	77.8				7	41.2				
Left	8	42.1				4	22.2				10	58.8				
Need to medicine for pain																0.540‡
Yes	9	47.4				9	50.0				11	64.7				
No	10	52.6				9	50.0				6	35.3				
Neer test																0.888‡
Positive	14	73.7				14	77.8				12	70.6				
Negative	5	26.3				4	22.2				5	29.4				
Hawkins-Kennedy test																0.401‡
Positive	16	84.2				13	72.2				11	64.7				
Negative	3	15.8				5	27.8				6	35.3				
Painful arc test																0.251‡
Positive	8	42.1				7	38.9				11	64.7				
Negative	11	57.9				11	61.1				6	35.3				

LG: Laser therapy group; UG: Ultrasound therapy group; CG: Control group; SD: Standard deviation; ROM: Range of motion; † Kruskal-Wallis test (α=0.05); ‡ Chi-square test (α=0.05).

TABLE 2
Outcome variables among the groups at baseline

	LG (n=19)			UG (n=18)			CG (n=17)			
	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	*p*†
Pain-activity (VAS, 0-10)	8.2±1.6	9.0	4-10	7.3±1.6	8.0	4-10	7.5±1.7	8.0	4-10	0.151
Pain-rest (VAS, 0-10)	3.6±2.6	3.0	0-9	2.8±2.1	3.0	0-7	2.5±2.0	2.0	0-7	0.424
Pain-nocturnal (VAS, 0-10)	7.3±2.3	8.0	0-10	7.0±2.7	8.0	0-9	6.8±2.9	8.0	0-10	0.960
SPADI-pain (0-50)	37.8±6.6	38.0	25-50	35.7±8.1	36.0	18-45	35.4±6.7	37.0	23-44	0.651
SPADI-disability (0-80)	49.7±17.0	52.0	18-74	48.1±13.6	49.0	18-67	46.5±14.3	48.0	17-72	0.737
SPADI-total (0-130)	87.5±22.4	90.0	44-124	83.9±21.2	86.0	37-111	82.0±20.3	82.0	45-116	0.713

LG: Laser therapy group; UG: Ultrasound therapy group; CG: Control group; SD: Standard deviation; VAS: Visual Analog Scale; SPADI: Shoulder Pain and Disability Index; † Kruskal-Wallis test (α=0.05).

groups in terms of all outcome measures over a three-month period (p>0.05) (Table 3).

DISCUSSION

In the present study, we assessed whether LLLT and US therapy combined with an HBE program were superior over each other and to evaluate their effectiveness in patients with SAIS versus an HBE regimen alone. According to our study results, LLLT and therapeutic US in combination with HBE and HBE programs alone were all effective in reducing pain and improving functions in patients with SAIS. When the treatment approaches were compared with the HBE program, LLLT was more effective in reducing pain and disability; however, no additional effect of US therapy was observed in terms of pain and disability in the short term. Consistent with these findings, systematic reviews have demonstrated that using laser treatment as an adjuvant therapy to exercise or in a physical therapy program can reduce pain and improve function.[6,25]

In the current study, we also examined the effectiveness of LLLT and therapeutic US versus HBE, as well as the impacts of the training programs on one another. Similar to our study, Saunders[13] found that laser therapy was effective for improving pain and disability compared to the control group. Therapeutic US enabled improvement in outcomes, but there was no significant difference between the US therapy group and the control group. Another randomized-controlled study comparing the effects of laser therapy to that of therapeutic US in combination with exercise revealed that pain, ROM, and shoulder functions were significantly improved in all groups.[14] Moreover, it should be noted that the type of baseline intervention, duration of treatment, and clinical variables of the patients included in that study were different from those of the current study. Additionally, most of the studies assessed the effects of LLLT and therapeutic US only after treatment.[13,14,26-30] However, the present study reported the results after the intervention period and at three months.

Ultrasound therapy had no added benefit when used in combination with exercise, in terms of pain reduction and self-reported function in this study. The findings are inconclusive and the level of recommendation is not high in the studies that evaluate the effect of therapeutic US for rotator cuff tendinopathy.[6] Similarly, the systematic review and meta-analysis by Desmeules et al.[31] concluded that therapeutic US was not superior to placebo and provided no additional benefit when combined with exercise in adults who suffered from rotator cuff tendinopathy. Additionally, the studies evaluating the effects of therapeutic US in combination with physiotherapy modalities showed improvements in pain, ROM, and functions and revealed that therapeutic US compared to sham US did not provide any further benefits when applied with other physical therapy interventions.[32,33] These discrepancies in the results of the studies can be explained by the differences in the intensity, frequency, and mode of US therapy and the application of additional moist heat or superficial cold.

There is conflicting evidence to support the use of LLLT in patients with subacromial shoulder pain.[12,34] Some studies have examined the effects of LLLT and placebo LLLT combined with an exercise program and shown no significant difference between the groups regarding pain severity, ROM, and upper extremity functions in patients with shoulder pain,[26,27] while others have reported the

TABLE 3
Changes in outcome values among the groups from baseline to the first and third month

	Measures				(1st month) *vs.* (Baseline)							(3rd month) *vs.* (Baseline)						
	Mean±SD				Within group	Between groups						Within group	Between groups					
										95% CI							95% CI	
	Baseline	1st month	3rd month	*p*†	*p*‡	*p*¥	Pairwise	*p*#	Cohen's d	Lower	Upper	*p*‡	*p*¥	Pairwise	*p*#	Cohen's d	Lower	Upper
Pain-activity (VAS, 0-10)																		
LG	8.2±1.6	5.2±2.2	4.6±2.9	<0.001	0.001	0.018	LG *vs.* CG	0.008*	0.868	0.184	1.553	<0.001	0.165	LG *vs.* CG	0.071	0.738	-0.062	1.414
UG	7.3±1.6	4.9±2.0	4.8±2.1	<0.001	<0.001		UG *vs.* CG	0.041	0.772	0.085	1.46	0.001		UG *vs.* CG	0.525	0.306	-0.361	.973
CG	7.5±1.7	6. 3(2.2	5.8±2.4	0.001	0.009		LG *vs.* UG	0.391	0.241	-0.407	0.887	0.007		LG *vs.* UG	0.221	0.426	-0.226	1.078
Pain-rest (VAS, 0-10)																		
LG	3.6±2.6	2.0±2.2	2.0±2.4	0.008	0.041	0.282	LG *vs.* CG	0.661	0.507	-0.158	1.172	0.019	0.242	LG *vs.* CG	0.661	0.514	-0.151	1.179
UG	2.8±2.1	1.7±1.7	1.7±1.7	0.001	0.007		UG *vs.* CG	0.525	0.560	-0.115	1.236	0.018		UG *vs.* CG	0.590	0.482	-0.190	1.155
CG	2.5±2.0	2.2±2.1	2.2±2.3	0.087	0.233		LG *vs.* UG	0.685	0.168	-0.478	0.814	0.397		LG *vs.* UG	0.916	0.426	-0.226	1.078
Pain-nocturnal (VAS, 0-10)																		
LG	7.3±2.3	4.5±2.6	4.1±3.0	0.001	0.004	0.094	LG *vs.* CG	0.049	0.517	-0.148	1.182	0.001	0.194	LG *vs.* CG	0.100	0.591	-0.078	1.259
UG	7.0±2.7	4.6±2.8	4.5±3.0	<0.001	0.001		UG *vs.* CG	0.153	0.506	-0.167	1.180	0.002		UG *vs.* CG	0.207	0.390	-0.279	1.059
CG	6.8±2.9	5.5±2.7	5.3±2.9	0.003	0.015		LG *vs.* UG	0.313	0.127	-0.518	0.772	0.016		LG *vs.* UG	0.538	0.241	-0.406	0.888
SPADI-pain (0-50)																		
LG	37.8±6.6	23.3±12.6	24.1±16.1	<0.001	0.002	0.010	LG *vs.* CG	0.003*	0.713	0.038	1.387	0.003	0.110	LG *vs.* CG	0.061	0.591	-0.078	1.259
UG	35.7±8.1	23.8±10.1	23.2±14.0	<0.001	<0.001		UG *vs.* CG	0.027	0.744	0.058	1.429	0.001		UG *vs.* CG	0.083	0.594	-0.083	1.271
CG	35.4±6.7	30.0±10.7	29.3±11.4	0.007	0.016		LG *vs.* UG	0.358	0.144	-0.502	0.789	0.025		LG *vs.* UG	0.799	0.013	-0.518	0.772
SPADI-disability (0-80)																		
LG	49.7±17.0	32.3±20.9	30.3±23.3	<0.001	0.002	0.023	LG *vs.* CG	0.012*	0.740	0.064	1.416	0.001	0.136	LG *vs.* CG	0.071	0.655	-0.016	1.327
UG	48.1±13.6	31.8±15.8	31.4±20.2	<0.001	<0.001		UG *vs.* CG	0.035	0.752	0.066	1.438	0.002		UG *vs.* CG	0.126	0.505	-0.168	1.178
CG	46.5±14.3	39.4±16.7	39.0±19.4	0.008	0.028		LG *vs.* UG	0.425	0.075	-0.570	0.720	0.100		LG *vs.* UG	0.620	0.146	-0.499	0.792
SPADI-total (0-130)																		
LG	87.5±22.4	55.6±33.3	53.7±39.0	<0.001	0.002	0.006	LG *vs.* CG	0.003*	0.907	0.220	1.594	0.001	0.336	LG *vs.* CG	0.165	0.499	-0.166	1.163
UG	83.9±21.2	55.7±25.6	54.6±33.8	<0.001	<0.001		UG *vs.* CG	0.020	0.860	0.168	1.553	0.001		UG *vs.* CG	0.351	0.367	-0.302	1.035
CG	82.0±20.3	70.5±25.4	68.3±30.5	0.014	0.037		LG *vs.* UG	0.221	0.154	-0.491	0.800	0.075		LG *vs.* UG	0.538	0.145	-0.500	0.791

SD: Standard deviation; CI: Confidence interval; VAS: Visual Analog Scalex; LG: Laser therapy group; UG: Ultrasound therapy group; CG: Control group; SPADI: Shoulder Pain and Disability Index; † Friedman; ‡ Wilcoxon S ranks; ¥ Kruskal-Wallis; # Mann-Whitney U test; * Statistically significant in the pairwise comparisons by Mann-Whitney U test with Bonferroni correction (p<0.017). Effect size, Cohen's d: 0.2 small, 0.5 medium, and 0.8 large effect.

positive effects of LLLT combined with an exercise program.[28,29] In addition, the comparison of these studies is difficult due to the different treatment parameters of the LLLT and exercise regimens used in the studies of patients with shoulder pain, which may contribute to the discrepancies in the results. Also, some studies have utilized LLLT over tender points rather than anatomical landmarks and shown no significant differences between LLLT and a placebo treatment.[26,27] Therefore, the additional benefit of LLLT might have been reduced by focusing on anatomical sites in the current study.[34]

The results of the study revealed that LLLT and therapeutic US combined with HBE were not superior to HBE alone in terms of all outcome measures at three months. Therefore, HBE may be sufficient for the treatment of SAIS for a three-month period. Similarly, systematic reviews reported that supervised and home-based progressive shoulder strengthening and stretching exercises as a part of a multimodal program of care for the rotator cuff and scapular muscles were effective for reducing pain and disability for the short-term management of SAIS with a variable duration.[35,36] Additionally, a recent systematic review demonstrated that supervised physiotherapy and home-based progressive shoulder strengthening and stretching exercises for the rotator cuff and scapular muscles were equally effective in patients with SAIS.[37] In this context, the additional effect of physical therapy interventions might have been enhanced by the profound effect of an HBE program.

Nonetheless, there are certain limitations to this study. First, this study has insufficient reporting of patients' characteristics regarding stage of SAIS and the lack of detailed recording of MRI findings. The causes of SAIS include a spectrum of pathology ranging from subacromial bursitis to full-thickness rotator cuff tears.[5] In this study, the patients with shoulder pain as a cause of full-thickness tear, calcific tendinosis, and adhesive capsulitis were excluded to create a more homogenous group. However, it should be considered that the response to physical therapy and rehabilitation may vary in patients depending on the stage of SAIS. Second, although the treating physiotherapist was blinded to the assessments and the data assessor was blinded to the group allocation, the patients were unblinded to the group allocation due to the nature of the intervention. Third, every physiotherapy intervention is naturally enriched by different contextual factors such as treatment features, healthcare setting features, and patient's features, that can influence the trajectory of outcomes toward a positive or a negative result.[38] Placebo, nocebo, and contextual-related effects have always been considered, while interpreting the results of the study.

In conclusion, LLLT with HBE can be considered a therapeutic option in terms of relieving pain and improving functionality for patients with SAIS in the short term. Ultrasound therapy with HBE can also improve the symptoms, but is not remarkably different from the HBE alone. However, LLLT and therapeutic US in combination with HBE are not superior to an HBE program alone at three months. Therefore, further large-scale, long-term studies are needed to establish the effectiveness of these treatments and learn more about the course of SAIS.

Ethics Committee Approval: The study protocol was approved by the Istanbul University Istanbul Medical Faculty Ethics Committee (date: 13.10.2017, no: 1152). The trial was prospectively registered on www.clinicaltrials.gov (NCT04779190). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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