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Original Article

Effects of acupuncture on pain and function in patients with subacromial impingement syndrome: A randomized sham-controlled trial

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ABSTRACT

Background: Subacromial impingement syndrome (SIS) is the most common cause of shoulder pain. Acupuncture is a traditional medicine that is effective on pain. This study aimed to evaluate the effect of acupuncture treatment on pain, function, range of motion (ROM) and quality of life compared to sham acupuncture in patients diagnosed with SIS.

Methods: A randomized, prospective, double-blinded, sham-controlled trial was conducted. In acupuncture group 40 participants received acupuncture treatment plus exercise therapy while in control group 40 participants received sham acupuncture plus exercise therapy. Primary outcomes included pain-rest, activity and night pain. Secondary outcomes included function [Shoulder Pain and Disability Index (SPADI) and The Disabilities of the Arm, Shoulder and Hand Score (Quick DASH)], ROM, and quality of life [The Western Ontario Rotator Cuff Index (WORC)] in patients with SIS.

Results: Both groups had significant improvements for pain-rest, activity night pain scores, SPADI, Quick DASH and WORC after treatment and at the first month follow-up. Significant improvements were recorded in the acupuncture group for all ROM after treatment and at the first month follow-up while in control group only in passive internal rotation. Acupuncture group had better improvements for Quick DASH, WORC and all ROM parameters after the treatment, as well as for all parameters except pain-night and passive flexion at the first month follow-up.

Conclusion: This study suggest that acupuncture treatment is a safe, effective and non-invasive treatment option in patients with SIS.

Trial registration: The study protocol is registered at clinicaltrials.gov (NCT05794633).

1. Introduction

Shoulder pain, with a prevalence range of 7–30%, is the third-most common musculoskeletal pain complaint in the world.[1] Subacromial impingement syndrome (SIS) is the most common cause of shoulder pain.[2] There are several conservative treatment options to manage SIS, such as exercise, physical therapy, manual therapy, Kinesio tape, heat and electricity application, nonsteroidal anti-inflammatory drugs (NSAID), cortisone injections, and acupuncture.[2,3]

Acupuncture is a traditional Chinese medicine (TCM) technique with analgesic efficacy. It offers treatment options for various pain conditions, both acute and chronic, including shoulder pain.[4] Several studies have reported a high level of evidence for the analgesic effectiveness of acupuncture.[5] Acupuncture has an anti-inflammatory effect on pain, as it prevents the formation of chemicals causing pain by affecting the painful signaling pathways; this effect can be explained by mechanisms such as interfering with peripheral sensitization mechanisms.[6,7] Its effect on shoulder pain has been reported in recent research as a pain factor and serum inflammatory factor reducer[9] that mediates the release of pain-relieving chemicals.[7] Although previous studies have demonstrated better results of acupuncture in patients suffering from shoulder pain compared to physiotherapy and sham acupuncture,[9-12] the effectiveness of acupuncture in the treatment of patients with shoulder pain remains controversial.[13] In addition, no clear conclusion has yet been reached on whether acupuncture treatment provides additional benefit to exercise in SIS.[14,15]

In addition, in acupuncture research, it is difficult to conduct double-blinded, randomized controlled studies, which are deemed as the gold standard in evidence-based medicine. Blinding is considered an important problem with contemporary acupuncture control methodologies as

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neither patients nor researchers are assured whether the patient is receiving an active intervention or a sham. A type of acupuncture needle that can be used as a sham has been developed to address this deficiency in recent research.[16] Nonetheless, no randomized controlled studies using sham needles in SIS have been found in the literature. The main purpose of our study was to evaluate the effectiveness of acupuncture treatment on pain in the short and medium term when compared with sham acupuncture in patients diagnosed with SIS.

2. Method

2.1. Trial design

A randomized, prospective, double-blinded, sham-controlled trial was conducted during June to November 2023 at the Fatih Sultan Mehmet Trial and Research Hospital, Istanbul, Turkey. The study protocol is registered at clinicaltrials.gov (NCT05794633).

2.2. Participants

Patients diagnosed with SIS admitted to the physical medicine and rehabilitation outpatient clinic were recruited for this study.

Inclusion criteria: Patients aged 20–65 years, who were diagnosed with SIS based on their history, results of physical examination, laboratory tests, radiological evaluation, and subacromial injection test, with pain according to visual analog scale (VAS) ≥4 and having been symptomatic for at least 6 weeks.

The enrolled patients were subjected to a subacromial injection test to confirm their diagnosis. For this purpose, 5 mL of 2% lidocaine was injected into the subacromial bursa using a 21-G needle under US guidance. All injections were administered by the same specialist. Both pain that was reported to reduce by 80%, and almost complete improvement in active and/or passive ROM 30 min following the injection was considered a positive subacromial injection test.[17,18]

Exclusion criteria: Patients with concomitant pathologies of the shoulder, such as calcific tendinitis, full-thickness tears of the rotator cuff tendons, adhesive capsulitis, osteoarthritis of the acromioclavicular joint, dislocations, and acute traumatic conditions; who have received physiotherapy and hyaluronic acid and/or corticosteroid injections in the preceding 3 months; who have cervical pain or other conditions such as fibromyalgia that can potentially confuse the clinical condition; who have malignancy, blood disorder, motor, neurologic, and/or sensory deficit in the upper extremity, pregnancy, an open wound near the shoulder, a local anesthetic allergy; and who had undergone acupuncture treatment before or/and surgical operation for the shoulder.

2.3. Intervention

The patients in the acupuncture group were administered acupuncture treatment 2 days/week for eight sessions using sterile stainless-steel needles (diameter 0.25 mm, length 40 mm, Hua-Long, China). Acupuncture points were selected according to the literature[9-12], TCM and WHO Standard Acupuncture points.[19] They were 2 tender points (ashi point) are located in the shoulder region, large intestine (Li) 15, 4; gallbladder (Gb) 21, 34; triple warmer (Tw) 5, 14; small intestine (Si) 9, and stomach (St) 38. First, the site was cleaned with alcohol. Acupuncture needles were then inserted into the affected shoulder area while the patient was lying on a stretcher in the lateral decubitus position. The needles were inserted using a plastic insertion tube during application. The needles were placed vertically 2–3-cm deep (Supplement 1). The duration of each session was 20 min, and the *de qi* sensation was obtained with the help of needle manipulations such as lifting, twirling, and thrusting. According to the description in the TCM literature, the *de qi* sensation is a feeling of warmth, paresthesia, tingling, or cramping in manipulated areas. During the sessions, the acupuncture needle was manually stimulated for at least 30 s every 5 min for a total of four manipulations per session. The acupuncture therapy practitioner was the manager of the TCM Unit of Fatih Sultan Mehmet Training and Research Hospital and has more than five years of experience in acupuncture.

The control group received sham acupuncture 2 days/week for a total of eight sessions using Park sham needles. Sham needles are formed by two plastic tubes, one of which slides into the other. These two plastic tubes are then attached to a flat disk that is used as the base. A double-sided sticky circle is used on the bottom of these to facilitate placement on the skin. The inner tube is placed in its extended (highest) position and sinks into the outer tube as the needle advances). The selected points (Supplement 1) were the same as for the acupuncture group patients (Li 15, Tw 14, Gb 21, Si 9, Tw 5, Li 4, Gb 34, St 38, and 2 ashi points). Each session lasted for 20 min. The acupuncturist pretended to manipulate the needle by rotating it every 5 min. Each participant was given detailed information about the type of study they were participating in, but they were blinded to the treatment arms during both the intervention and follow-up phases. To ensure the implementation of the blinding method, all participants were treated independently and avoided contact with each other. The assessor was blinded to the treatment type administered to participants. The participants, assessors, statisticians, and all relevant investigators were blinded to which patient group received which treatment during the study and were maintained blinded throughout the trial. Only the practitioner knew the treatment branches.

All patients received cold pack application on the affected shoulder using cold pack gels (thrice a day, 20 min/session), a home exercise program consisting of five sets of Codman pendulum exercises (5 min/set), daily activity restriction requiring the overhead use of hands, and not sleeping on the affected shoulder during the treatment. Patients are encouraged to participate in their home exercise program at each session. After the treatment, the participants were asked to continue their exercise program for another 1 month by adding a shoulder strengthening exercise program (15 repetitions, thrice a day). All adverse events were investigated using the adverse event form and recorded during each visit.

2.4. Outcome measures

2.4.1. Primary outcomes

The primary outcomes were pain-rest, activity and night.

Pain: Every group was evaluated for shoulder pain using a VAS for activity, rest, and night pain. Patients were asked to rank their pain severity on a 10-point scale, where 0 = no pain, 5 = moderate pain, and 10 = intolerable pain.[20]

2.4.2. Secondary outcomes

The secondary outcomes were shoulder function, shoulder range of motion and quality of life.

Patient evaluation was performed before and immediately after the treatment and then at 1 month after the completion of the treatment. The same physiatrist who was blinded to the randomization process and treatment protocols evaluated all patients.

Shoulder range of motion: The participants were examined for shoulder ROM in eight different types of motions, namely active and passive flexion, internal and external rotation, and abduction with a goniometer.

Function: All groups were evaluated for shoulder function using the Shoulder Pain and Disability Index (SPADI) and Questionnaire Quick Disability of the Arm, Shoulder, and Hand (Quick DASH). SPADI is a self-administered survey containing two dimensions, one for pain and another for functional activities.[21] Quick DASH is a questionnaire measuring an individual's ability to complete tasks, absorb forces, and severity of symptoms with 11 items.[22] High scores on both scales indicated a lower function.[21,22]

Quality of life: All groups were evaluated for quality of life with The Western Ontario Rotator Cuff Index (WORC). WORC is used to assess the quality of life and is a condition-specific self-reported instrument.

The total score ranges from 0 to 2100, with higher scores representing lower quality of life.[23]

2.5. Randomization methods and blinding

First, patients who showed an interest in participating in our trial were interviewed. After recruiting, a random number table was generated on the computer using SPSS 22 to divide the participants into acupuncture and control groups (1:1 ratio). Sealed envelopes were used for randomizing numbers, and another independent administrator in-charge distributed the envelopes to the physicians. Participants were assigned to either the acupuncture or the control group according to random digital cards in the envelopes.

2.6. Sample size

Sample size was calculated based on a previous study by Guerra de Hoyos[9] using the same primary outcome measure (pain VAS) among randomized controlled clinical trials of acupuncture for shoulder pain. As a result of the Power analysis performed using the G*Power program, the effect size for the VAS pain parameter was 0.68690 and standard deviation: 2.8. The number of samples determined for Power: 0.80 and a: 0.05 was determined to be minimum n: 35 for each group. 40 people were included in each group, assuming that there would be 10% dropouts from the study.

2.7. Ethical statement

Approval for the study was given by the Research Ethics Committee of Yeditepe University (protocol no. 1180). Every patient provided his/her informed consent before inclusion in the study. The reporting of this study followed the ethical principles of the Declaration of Helsinki, Consolidated Standards of Reporting Trials (Supplement 3), and Standards for Reporting Interventions in Controlled Trials of Acupuncture guidelines.

2.8. Statistical analyses

The behavior of the quantitative variables was specified using measures of centralization and variance: Mean ± Standard deviation. Fisher Exact and Chi-square test were used to determine differences in proportions or relationships between categorical variables. To show the behavioral differences of group averages; in cases where normality and homogeneity assumptions were not met, the Mann-Whitney U-Test method was used. The Friedman test was used to evaluate whether the difference between dependent measurements made between different time points or conditions was statistically significant. Wilcoxan Rank Sum Test was used to examine whether the change in measurement values of the same individuals at different times was different from 0. MICE (Multiple Imputation by Chained Equations) method, an advanced data imputation technique, was used to estimate missing data. Statistical significance was determined as $p = 0.05$ for all cases. Statistical analyzes were performed with the IBM SPSS package program.

3. Results

A total of 92 volunteers were evaluated during the study period. From this group, four were excluded as they did not meet the criteria established at the baseline and another six because their subacromial injection tests were negative; two volunteers refused to participate after being informed about the details of the study. The remaining 80 participants were randomly assigned to the two groups of acupuncture ($n = 40$) and control ($n = 40$). Of the total, 35 and 36 individuals in the acupuncture and control groups, respectively, completed the study. 9 participants (5 in the acupuncture group and 4 in the control group) could not complete the 8-session treatment due to inability to continue exercise, unable to contact or lack of time. (Supplement 2). In all cases, the participants complained of shoulder pain for at least 6 weeks.

Pretreatment data indicated no meaningful difference among the groups in terms of demographic characteristics (Table 1). Statistically significant improvements were recorded in the acupuncture group for active and passive flexion, abduction, and internal and external rotation degrees after treatment and at the 1-month follow-up when compared with those before treatment. In the control group, significant improvements were observed only in the degrees of passive internal rotation (Table 2). Comparison of the groups displayed significantly superior results for the acupuncture group, especially for Quick DASH, WORC, and all ROM parameters after the treatment, as well as for all parameters, except VAS night pain, and passive flexion, at the 1-month follow-up (Supplement 5). No adverse events were observed in either of the groups.

4. Discussion

As per the present results, eight sessions of acupuncture treatment in patients with SIS provided significantly more improvement in terms of pain, function, shoulder ROM, and quality of life than the sham acupuncture.

The effectiveness of acupuncture on pain has been demonstrated across studies.[24] Past studies compiling the effectiveness of acupuncture treatment in musculoskeletal system diseases have focused particularly on the effectiveness on pain, which is the main complaint.[25-28] However, the additional improvement has been attributed to verum acupuncture rather than sham acupuncture; although the difference is statistically significant, it is of less clinical significance considering that the placebo response may be responsible for most of the proven benefits of acupuncture treatment.[28] The latest systematic review emphasizes that acupuncture has short-term benefits on shoulder pain, but may be superior to traditional drug treatment in terms of pain and function outcomes. However, there is little evidence to support or refute the use of acupuncture for shoulder pain because of the paucity of studies on specific diseases, small sample sizes, study blinding issues, incomplete intervention descriptions, and the lack of methodologically diverse interventions. It has also been reported that better-designed clinical studies are needed to translate the current results into clinical practice.[13,28,29]

In several randomized controlled clinical trials demonstrating the effectiveness of acupuncture for chronic shoulder pain, acupuncture has been reported to be effective in improving pain and shoulder function.[8-12,30-33] However, there are a few studies demonstrating the effectiveness of acupuncture in patient groups based on the differential diagnosis of specific diseases that may induce shoulder pain, such as frozen shoulder, impingement syndrome, rotator cuff disease, and biceps tendinopathy.[12,31–34] In addition to obtaining a diagnosis of SIS by history, laboratory tests, and radiological evaluation, we confirmed the diagnosis of SIS via subacromial injection testing.

There is no clear conclusion about whether acupuncture treatment provides additional benefits to exercise in SIS.[14] This study suggested that acupuncture treatment was more effective on pain, function, shoulder ROM, and quality of life than sham acupuncture. While the improvement in pain, function, ROM, and quality of life continued in the acupuncture group, it did not match that in the control group at the 1st month follow-up.

A comparison of various studies on acupuncture showed differences in terms of the selection of the acupuncture points. In our study, for instance, we selected local points related to pathology in the shoulder region and specific points for shoulder and muscle injuries according to TCM. However, in Vas et al.'s study,[35] only the stomach 38 point was used for 4 weeks in the intervention group, while in Guerra de Hoyos et al's[9] study, two points were local (Li 15 and Tw 14) and two were distal (Gb 34 and extra point Zhongping). Garrido et al.[12] chose Li 15, Li16, Tw 14, and Si 9 as the local points and St 38 and Li 4 as the distal points. Zhang et al. examined the effect of manual acupuncture applied to the contralateral region.[36] Although the diversity of points used

Table 1
Summary of demographics parameters and features related to pain.

Variables		Acupuncture (N = 40)	Sham acupuncture (N = 40)	P
Age (mean ± SD)		51.35 ± 8.73	53.33 ± 7.76	0.236[1]
BMI (mean ± SD)		28.58 ± 5.43	28.65 ± 5.0	0.954[1]
Sex (n)	Female	32	26	0.211[2]
	Male	8	14	
Education (n)	Illiterate	4	2	0.068[3]
	Primary school	22	19	
	Secondary school	1	8	
	High school	7	9	
	University	6	2	
Comorbidity	Diabetes	7	8	0.99[2]
	Hypertension	5	12	0.101[2]
	Hypothyroidism	4	4	0.99[3]
	Hyperthyroidism	0	1	0.99[3]
Smoking	Never smoking	31	26	0.194[3]
	Smoking	9	11	
	Previous smoking	0	3	
Alcohol	None	40	39	0.99[3]
	Less than once a month	0	1	
Overhead activity	Yes	31	33	0.78[2]
	No	9	7	
Hand choice	Right	38	38	1.000[3]
	Left	2	2	
Affected side	Right	27	27	1.000[2]
	Left	13	13	
Worst pain time	Morning	4	2	0.462[3]
	Evening	2	2	
	Midday	0	1	
	Night	22	21	
	Whole day	3	8	
	Indefinite	9	6	
Night pain	Yes	32	38	0.091[2]
	No	8	2	

[1] Mann Whitney U Test
[2] Pearson Chi-Squared Test
[3] Fisher Exact Test;BMI, body mass index.

in the literature causes difficulties in creating a methodology, Lathia et al.'s study revealed a significant improvement when compared with the control group through personalized and standard protocols. In our study, we partially personalized the treatment protocol by applying the standard protocol to patient-specific tender points. The duration of the treatment applied in our study was 4 weeks. Although there are a few studies in the literature that have applied longer duration and more sessions of treatment,[12] the treatment duration and number of sessions are generally similar to that adopted in our study.[9,10,12] We found that 4 weeks was sufficient to achieve the therapeutic effect and that the improvements in pain, function, ROM, and quality of life parameters of the participants in the treatment group continued to be greater than those in the control group at the 1st-month follow-up. Our study findings may thus support the existing results to avoid confusion in the literature regarding session and duration.

Endogenous opioid peptides, the serotoninergic descending inhibitory pathway, and the autonomic nervous system are accepted as mechanisms of the effect of acupuncture on pain.[37] In addition, it has been observed that certain acupuncture points are particularly effective on hyperalgesia when compared with sham applications.[38,39] Moreover, some studies have reported local and widespread hyperalgesia in SIS.[40,41] Hyperalgesia is associated with higher pain perception in cases of shoulder pain.[42] These past studies suggest that central sensitivity may need to be addressed in addition to interventions on biomechanical or anatomical pathologies to efficiently manage SIS. This may be one of the mechanisms through which acupuncture was effective in SIS in our study. We applied to the St 38 point in the tibialis anterior muscle, which is known as the shoulder-specific point in TCM, in the area away from the shoulder and to the two most painful points (ashi points) in the shoulder area. We also used the GB34 point, which has been shown to have antihyperalgesic activity in animal models[41] and is the master point of the muscles according to TCM. The more significant improvement observed in the acupuncture group may also be explained by the decrease in hyperalgesia in these regions.

Moreover, Xu et al. emphasized that apparent pain relief after acupuncture treatment in patients with chronic neck and shoulder pain may be related to an increase in their periaqueductal gray-based functional connectivity.[43] Harris et al. showed, through their neuroimaging studies, that acupuncture treatment stimulates short-term increases in mu-opioid receptor (MOR) binding potential as well as long-term (a month later) increases in multiple pain and sensory processing regions of the brain. These effects on MOR-binding potentials were undetected in the sham acupuncture group.[44] The continued improvement at the end of the first month of our study supports these findings.

The significant placebo effect of acupuncture contributes to the therapeutic effect demonstrated in previous studies.[45,46] The placebo effect may be explained by the patient's expectation of the treatment and is affected by factors such as the placebo method applied and patient–doctor interaction.[48] In our study, the placebo effect of acupuncture undoubtedly contributed to the improvements seen in both the acupuncture and control groups. Although more evidence is warranted, studies have shown that feeling *de qi* yields better therapeutic effects.[47] In our study, the superior improvement observed in the acupuncture group wherein the *de qi* sensation was obtained supports this effect.

In a meta-analysis, it was stated that smaller effect sizes were observed in sham-controlled trials that used a penetrating needle for sham and in trials with a high intensity of intervention in the control group. Nevertheless, the effectiveness of acupuncture cannot be explained only by a placebo.[28] A strength of our study is that the control group received a sham injection to blind the participants and prevent needle-specific

Table 2
Pain on VAS scores, joint range of motion, function and quality of life within and between groups.

Outcomes		Acupuncture (*N* = 40)	Sham acupuncture (*N* = 40)	P
Pain rest	Pre	5.55 ± 3.84	3.75 ± 2.69	0.014*
	Post	2.80 ± 2.33	2.40 ± 1.86	0.495
	1-month	1.80 ± 1.99	2.75 ± 2.32	0.062
Pain activity	Pre	8.18 ± 1.77	8.25 ± 2.01	0.575
	Post	4.58 ± 2.62	5.55 ± 2.19	0.074
	1-month	3.73 ± 2.53	5.35 ± 2.49	0.006*
Pain night	Pre	6.55 ± 3.55	6.85 ± 2.52	0.789
	Post	3.55 ± 2.5	4.43 ± 2.55	0.166
	1-month	3.00 ± 2.40	4.78 ± 3.22	0.014*
Active flexion	Pre	149.75 ± 33.09	161.50 ± 27.32	0.064
	Post	167.75 ± 23.37	164.50 ± 24.9	0.66
	1-month	173.00 ± 17.86	165.00 ± 23.75	0.092
Passive Flexion	Pre	165.25 ± 22.76	172.50 ± 16.60	0.085
	Post	172.25 ± 19.93	173.50 ± 16.73	0.983
	1-month	173.75 ± 17.2	173.25 ± 16.70	0.611
Active Abduction	Pre	146.25 ± 31.52	146.25 ± 34.54	0.655
	Post	161.00 ± 30.70	151.50 ± 31.67	0.216
	1-month	168.00 ± 25.54	155.00 ± 28.82	0.011*
Passive Abduction	Pre	164.25 ± 22.52	171.00 ± 18.37	0.12
	Post	171.25 ± 20.15	171.25 ± 18.28	0.447
	1-month	173.75 ± 16.44	171.50 ± 18.19	0.336
Active internal rotation	Pre	63.88 ± 21.44	69.50 ± 19.86	0.228
	Post	76.38 ± 20.38	71.75 ± 17.52	0.085
	1-month	79.38 ± 18.61	76.00 ± 15.66	0.071
Passive internal rotation	Pre	76.5 ± 18.58	80.25 ± 14.59	0.335
	Post	82.25 ± 14.59	82.00 ± 13.63	0.453
	1-month	83.50 ± 14.60	85.50 ± 11.76	0.995
Active external rotation	Pre	72.38 ± 23.75	85.25 ± 12.81	0.003*
	Post	80.25 ± 18.57	87.75 ± 8.32	0.065
	1-month	85.00 ± 14.81	87.75 ± 8.32	0.682
Passive external rotation	Pre	82.63 ± 12.76	87.50 ± 9.27	0.016*
	Post	85.50 ± 10.37	88.50 ± 8.02	0.082
	1-month	87.75 ± 7.33	88.50 ± 8.02	0.411
SPADI total	Pre	68.57 ± 16.87	66.88 ± 20.20	0.806
	Post	40.57 ± 23.19	46.89 ± 23.05	0.222
	1-month	32.35 ± 23.67	44.43 ± 24.96	0.031*
Quick DASH	Pre	58.10 ± 17.68	56.99 ± 18.24	0.954
	Post	32.34 ± 19.08	42.19 ± 21.85	0.051
	1-month	25.10 ± 18.18	40.31 ± 24.30	0.004*
WORC	Pre	1506.75 ± 417.29	1421.95 ± 442.18	0.791
	Post	923.50 ± 470.11	1053.25 ± 485.39	0.231
	1-month	722.50 ± 475.52	994.25 ± 547.95	0.023*

* , $P < 0.05$; Quick DASH, Questionnaire Quick Disability of the Arm, Shoulder, and Hand; SPADI, Shoulder Pain and Disability Index; WORC, The Western Ontario Rotator Cuff Index.

physiological effects. Intervention without penetration with sham needles is supported by international guidelines as it eliminates the danger of a neurological response in the control group that could have impacted our study.[48]

Nonetheless, our study has some limitations. The follow-up time was short. Therefore, the effectiveness of acupuncture in the long term could not be measured. Larger-scale multicenter studies can yield clearer results. As a natural result of acupuncture studies, the practitioner could not be blinded. Instead, the assessors and participants were blinded.

In conclusion, our study validates that acupuncture had superior effects compared with sham in patients with SIS. This study may contribute to eliminating the uncertainty in the literature regarding the frequency and duration of acupuncture treatment. Our findings suggest that acupuncture is a safe, effective, and noninvasive treatment option for patients with SIS.

CRediT authorship contribution statement

Duygu Silte Karamanlioglu: Conceptualization, Investigation, Writing – original draft. **Meryem Yilmaz Kaysin:** Data curation, Software. **Feyza Akan Begoglu:** Methodology, Visualization. **Pinar Akpinar:** Supervision, Writing – review & editing. **Feyza Unlu Ozkan:** Software, Validation. **Ilknur Aktas:** Writing – review & editing.

Declaration of competing interest

The authors report there are no conflict of interests to declare.

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Ethical statement

The study was approved by the Research Ethics Committee of Yeditepe University, under protocol no 1180. Every patient has given his/her informed consent prior to inclusion in study.

Data availability

The data that support the findings of this study are available from the corresponding authors, upon reasonable request

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2024.101049.

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