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ORIGINAL RESEARCH

The Effectivity of Prolotherapy Treatment in Shin Splint: A Randomized Controlled Study

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Abstract
Objective: Shin Splints (SS) is one of the most common reasons for post-exercise pain especially in athletes and in army recruits. The purpose of this randomized controlled clinical study is to evaluate the effectivity of prolotherapy for the treatment of SS.
Material-Method: Forty-four patients with shin splints have symptoms more than three months were divided into prolotherapy (n=22) and exercise (n=22) groups. Ultrasound-guided injections were performed under aseptic conditions using a 27 G needle with a solution of 6.6 ml 15% dextrose and 0.4 ml lidocaine to the posteromedial border of the tibia through up to seven different points (1 cc solution to each point) in the prolotherapy group for 3 times in every 21 days. The exercise program was given for 12 weeks to exercise group. The VAS and functional scores were performed at the beginning, 3, 6 and 24 weeks.
Results: There were statistically significant differences in Lower Extremity Functional Score after 3, 6, 24 weeks, and VAS after 3 and 6 weeks of the treatment ($p= 0.023$, $p=0.006$, $p=0.005$, $p=0.013$, $p<0.001$ respectively).
Conclusion: Prolotherapy can be preferred in the treatment of shin splints because of its rapid results. Also, an easy and inexpensive application method.
Keywords: Shin Splints, Athletic Injuries, Pain

INTRODUCTION

‘‘Shin Splints’’ (SS) is one of the most common reasons for post-exercise pain especially in athletes[1], and also in army recruits[2]. Also known as Medial Tibial Stress Syndrome[1]. Some epidemiologic trials have showed that 13,1% of the sports injuries in the runners and 22% of the aerobic dancers are SS[3] and 5.67% in army recruits[4]. SS is aforethought to be an overuse injury that the most effective on the training of the military personnel[4]. SS reasons pain, disability, and impaired quality of life because of progressive pain more and important complications if not treated properly[5]. There are too many considerations about the pathophysiology; such as periostitis of the tibia because of tibial strain, the tibialis posterior dysfunction, tibialis anterior, and soleus muscles are also usually blamed. But, new evidence demonstrates that SS generally includes any or some of the tibial tendinopathy, periostitis, periosteal remodeling, and stress reaction[6,7]. SS has the longest recovery time with 19.8% of total recovery days in musculoskeletal injuries of the army recruits[4].
Various treatment methods have been reported in the treatment of SS as; Rest and ice in the early phase, modifying training program, low-impact and cross-training exercises, ESWT, acupuncture, steroid injections and splinting or bracing. There are some considerations about recently popular methods used for musculoskeletal conditions such as dry-needling, blood injections (autologous or platelet-rich plasma) and prolotherapy for the treatment of SS[5]. But, there is no published

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randomized controlled trial with these various injection techniques for SS in the literature[5].

Prolotherapy has proven to be a safe and effective procedure because of its healing or regeneration ability for soft tissues when used in chronic musculoskeletal conditions such as low back pain, tendinopathy, osteoarthritis[8,9]. After an injury if an inadequate repair occurs, pain and disability can emerge from degenerated ligaments, tendons, cartilage, and enthesis. These structures can be treated by using the Prolotherapy injection method[9]. Hypertonic dextrose is one of the most solution using in prolotherapy[9,10].

Despite a variety of treatment methods mentioned before on the treatment of SS, and there is no evidence about prolotherapy in the treatment of this condition. The purpose of this randomized controlled clinical study is to evaluate the effectivity of prolotherapy for the treatment of SS.

MATERIALS AND METHODS

Subjects

This randomized controlled clinical study recruited forty-four patients with shin splints who have symptoms more than 6 months and the diagnosis confirmed by using a three-phase dynamic Tc99m - MDP bone scintigraphy or MRI between February 2015 - 2016. All patients are cadets except for one sergeant. Patients were divided into prolotherapy (n=22) and exercise (n=22) groups with a computer-assisted randomization program.

Inclusion criteria were; patients with the ages of 18-30 years and at least 6 months of symptoms. Exclusion criteria of the patients were; the previous operation on the heel, patients who had received local corticosteroid injection within 12 weeks, the bleeding tendency, infection evidence in the lower limbs, pregnancy, nerve entrapment syndromes such as the tarsal tunnel syndrome and missing follow-ups.

The study's ethics were approved by Ankara Numune Education and Research Hospital Ethics Committee of Clinical Trial (Study Number: E. Kurul-E-15-385/29.01.2015). Each patient who was enrolled in this study has signed informed consent. The study was made in accordance with the Helsinki Declaration Principles.

One patient in the prolotherapy group and seven patients in the exercise group were excluded from the study due to missing follow-ups (Figure 1).

Prolotherapy injections

Ultrasound-guided injections were performed under aseptic conditions using a 27 G needle with a solution of 6,6 ml %15 dextrose and 0,4 ml lidocaine to the posteromedial border of the tibia through up to seven different points (1 cc solution to each point) in the prolotherapy group for 3 times in every 21 days.

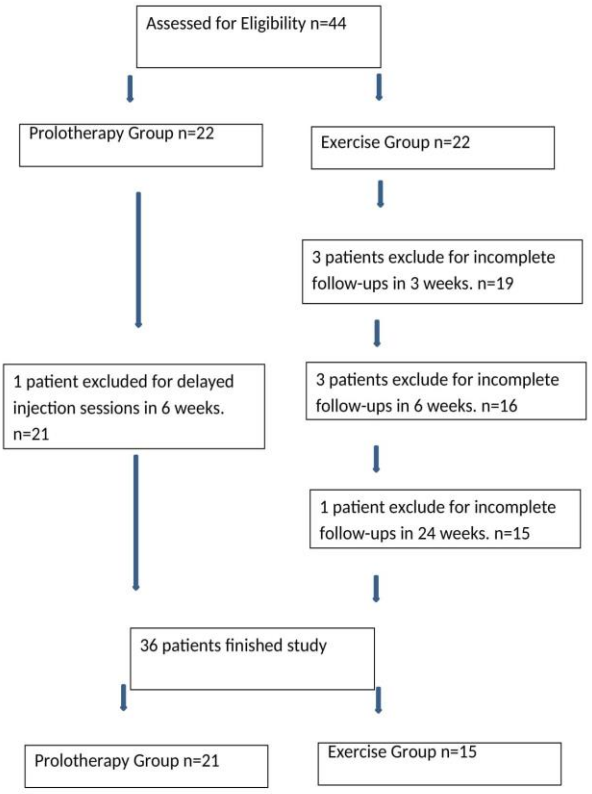

Figure 1. Flowchart of the study.

Patients were enrolled a home exercise program consists of soleus, gastrocnemius, and hamstring muscles stretching exercises. These exercises were started after the third day of the injections. Additionally, patients were ordered to refrain from any heavy loading activity for three days of the injections. We advised patients not to use anti-inflammatory agents.

Exercise program

The exercise program was given to Exercise group, 3 seasons per week for 12 weeks at a sports medicine department. The program started with stretching exercises of soleus, gastrocnemius, and hamstring for the first two weeks. Strengthening exercises were added in the third week; toe curl, heel drop, monster walk, toe walk, single-legged bridge. All exercises were started with 3 sets of 8 repetitions and increased to 15 repetitions.

We suggested to decreased running distance and

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recommended biking and swimming instead of running.

Assessments and outcomes

We used VAS (Visual Analog Scale), Lower Extremity Functional Score (LEFS) and Lysholm Scores for assessing pain and functions of the patients. The VAS and functional scores were performed at the beginning, 3, 6 and 24 weeks. Patients were asked for side effects at every control.

VAS score

This subjective assessment was scored between 0 and 10 points (0: no pain and 10: severe pain) to evaluate pain.

Lower Extremity Functional Score (LEFS) was used to evaluate the lower extremity functions and consist of 20 questions and 4 subgroups. The Turkish version of the Lower Extremity Functional Scale is shown to be a valid and reliable questionnaire[11].

Lysholm Score was a 100 point questionnaire, consist of 8 items and evaluate pain and function. Each 25 points scores are related to pain and instability.

Statistical analyses

The IBM SPSS Statistics version 25 was used for statistical analysis in this study. The data were presented as number, percent and mean ± SD. Descriptive statistics were defined as mean ± standard deviation and minimum-maximum for continuous variables and case number (n) and percentage (%) for nominal variables. Wilcoxon Signed Ranks Test was used for comparison of intra-group VAS scores and the Mann-Whitney U test was used for comparison of between groups VAS scores. The $p<0,05$ was considered to report a statistically significant difference.

RESULTS

Age, gender, side and duration of symptoms of the groups were shown in Table 1. There were statistically significant differences in LEFS after 3, 6, 24 weeks, and VAS after 3 and 6 weeks of the treatment ($p= 0.023$, $p=0.006$, $p=0.005$, $p=0.013$, $p<0.001$ respectively) (Table 2). There were no statistical differences within-group comparison, except for the Lysholm score before and after 3 weeks of the treatment in the exercise group ($p=0.173$) (Table 3). The comparisons of the groups' LEFS scores were shown in Figure 2 and VAS scores in Figure 3.

Table 1. Characteristics of the groups.

		Prolotherapy Group		Exercise Group	
		Mean±sd	**Min-Max**	**Mean±sd**	**Min-Max**
Age, year		20.8±3.3	18-30	20.4±1.7	18-22
Sex, n (%)	**Male**	19 (90.5%)		14(93.3%)	
	Female	2 (9.5%)		1 (6.7%)	
Side, n (%)	**Right**	11 (52.4%)		8 (53.3%)	
	Left	10 (47.6%)		7 (46.7%)	
Duration, month		6.7±2.4	4-12	7.0±2.2	4-12

Table 2. Functional and VAS scores between groups.

	Prolotherapy Group		Exercise Group		P Value
	Mean±sd	**Min-Max**	**Mean±sd**	**Min-Max**	
LEFS beginning	47.1±14.7	24-67	46.8±15.3	24-67	0.950
LEFS 3 weeks	59.4±12.7	37-73	50.7±14.5	24-71	0.023
LEFS 6 weeks	69.0±8.5	46-77	60.4±11.4	37-71	0.006
LEFS 24 weeks	78.5±2.5	70-80	74.6±4.3	67-80	0.005
LYS beginning	75.1±17.0	37-94	75.6±17.3	37-91	0.950
LYS 3 weeks	84.9±9.7	62-100	81.2±9.3	62-94	0.180
LYS 6 weeks	93.4±6.0	78-100	88.8±9.8	62-100	0.180
LYS 24 weeks	99.5±1.5	94-100	98.4±2.6	94-100	0.374
VAS beginning	7.8±1.3	5-10	7.2±1.5	5-10	0.252
VAS 3 weeks	5.2±1.8	1-9	6.8±1.5	5-9	0.013
VAS 6 weeks	3.1±1.5	1-7	5.2±1.5	3-8	<0.001
VAS 24 weeks	1.1±0.4	1-2	1.6±0.9	1-4	0.238

Mann Whitney U test was used.
LEFS: Lower Extremity Functional Score; LYS: Lysholm Score; VAS: Visual Analog Score

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Table 3. Functional and VAS scores of the groups.

	Prolotherapy Group			Exercise Group		
	Mean±sd	**Min-Max**	**P Value**	**Mean±sd**	**Min-Max**	**P Value**
LEFS-b	47.1±14.7	24-67	<0.001	46.8±15.3	24-67	0.008
LEFS-3 w	59.4±12.7	37-73		50.7±14.5	24-71	
LEFS-b	47.1±14.7	24-67	<0.001	46.8±15.3	24-67	0.001
LEFS-6 w	69.0±8.5	46-77		60.4±11.4	37-71	
LEFS-b	47.1±14.7	24-67	<0.001	46.8±15.3	24-67	0.001
LEFS-24 w	78.5±2.5	70-80		74.6±4.3	67-80	
LEFS-3 w	59.4±12.7	37-73	0.001	50.7±14.5	24-71	0.006
LEFS-6 w	69.0±8.5	46-77		60.4±11.4	37-71	
LEFS-3 w	59.4±12.7	37-73	<0.001	50.7±14.5	24-71	0.001
LEFS-24 w	78.5±2.5	70-80		74.6±4.3	67-80	
LEFS-6 w	69.0±8.5	46-77	<0.001	60.4±11.4	37-71	0.001
LEFS-24 w	78.5±2.5	70-80		74.6±4.3	67-80	
LYS-b	75.1±17.0	37-94	0.001	75.6±17.3	37-91	0.173
LYS-3 w	84.9±9.7	62-100		81.2±9.3	62-94	
LYS-b	75.1±17.0	37-94	<0.001	75.6±17.3	37-91	0.003
LYS-6 w	93.4±6.0	78-100		88.8±9.8	62-100	
LYS-b	75.1±17.0	37-94	<0.001	75.6±17.3	37-91	0.001
LYS-24 w	99.5±1.5	94-100		98.4±2.6	94-100	
LYS-3 w	84.9±9.7	62-100	0.003	81.2±9.3	62-94	0.009
LYS-6 w	93.4±6.0	78-100		88.8±9.8	62-100	
LYS-3 w	84.9±9.7	62-100	<0.001	81.2±9.3	62-94	0.001
LYS-24 w	99.5±1.5	94-100		98.4±2.6	94-100	
LYS-6 w	93.4±6.0	78-100	0.001	88.8±9.8	62-100	0.001
LYS-24 w	99.5±1.5	94-100		98.4±2.6	94-100	
VAS-b	7.8±1.3	5-10	<0.001	7.2±1.5	5-10	0.034
VAS-3 w	5.2±1.8	1-9		6.8±1.5	5-9	
VAS-b	7.8±1.3	5-10	<0.001	7.2±1.5	5-10	0.001
VAS-6 w	3.1±1.5	1-7		5.2±1.5	3-8	
VAS-b	7.8±1.3	5-10	<0.001	7.2±1.5	5-10	0.001
VAS-24 w	1.1±0.4	1-2		1.6±0.9	1-4	
VAS-3 w	5.2±1.8	1-9	<0.001	6.8±1.5	5-9	0.002
VAS-6 w	3.1±1.5	1-7		5.2±1.5	3-8	
VAS-3 w	5.2±1.8	1-9	<0.001	6.8±1.5	5-9	0.001
VAS-24 w	1.1±0.4	1-2		1.6±0.9	1-4	
VAS-6 w	3.1±1.5	1-7	<0.001	5.2±1.5	3-8	0.001
VAS-24 w	1.1±0.4	1-2		1.6±0.9	1-4	

Wilcoxon test was used.
LEFS: Lower Extremity Functional Score; b: beginning; w: week; LYS: Lysholm Score; VAS: Visual Analog Score

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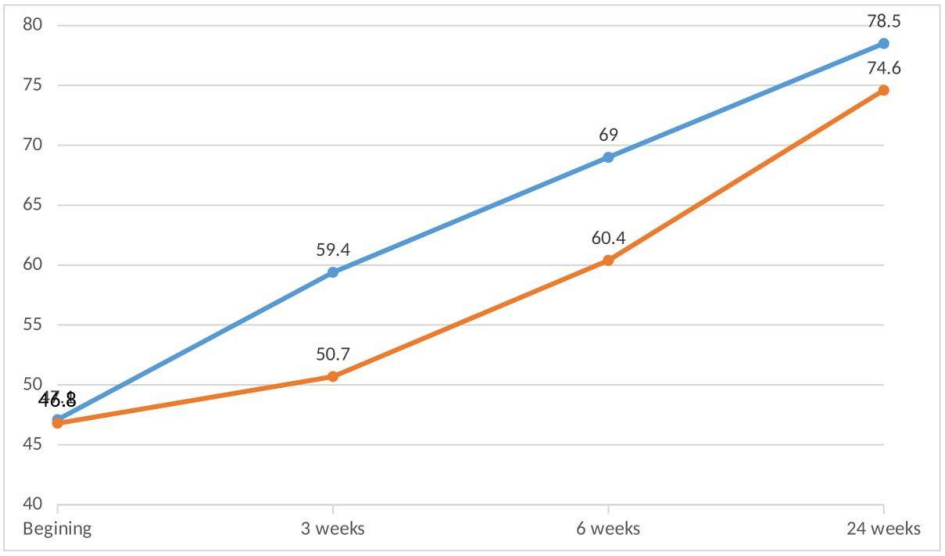

Figure 2. Lower extremity functional scores (LEFS) of the groups. Blue line for the prolotherapy group and orange line for the exercise group

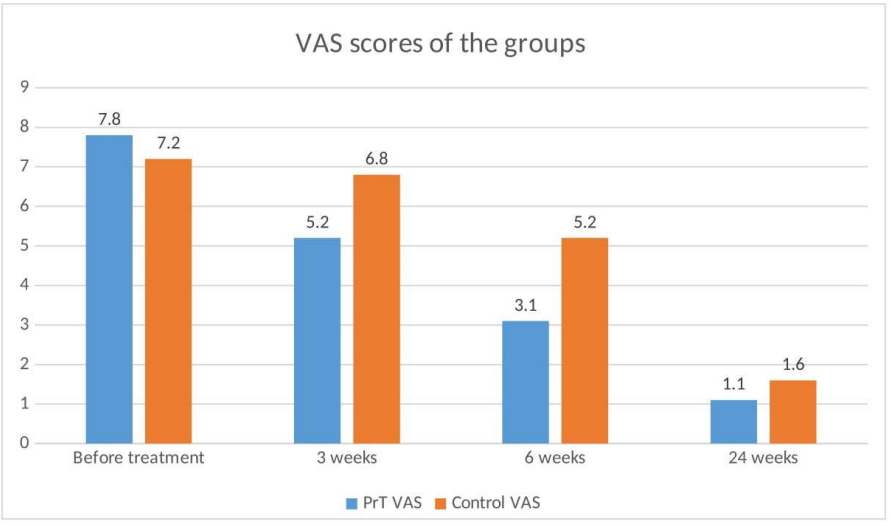

Figure 3. VAS scores of the groups

DISCUSSION

Our study results demonstrated that the prolotherapy shows a significant difference in LEFS and VAS scores after the first application compared to the exercise group, and the LEFS score continued to increase until 6 months later. The VAS score was similar at 6 months. The Lysholm score was similar in each group. We think the reason for this similarity is that the Lysholm score is focused on pain and instability and is not as detailed as the LEFS. In the within-group comparison, occurring of no difference in the Lysholm score between the beginning of treatment and after 3 weeks in the exercise group indicates that rapid recovery was not achieved only by exercise.

SS generally results in loss of the training time and affecting an army recruit's physical and mental health. Time, health and financial loss occur[4,12]. Therefore, there are studies on this subject using different treatments to date. In the last 5 years, a study to prevent lower extremity overuse injuries in

naval recruits suggests that prefabricated foot orthoses may be useful to reduce the incidence of lower extremity injuries[12]. However, in another study, targeted manual techniques to reduce pain and functional disorders were applied to patients, and this method was found to be effective in the treatment of acute shin splint[13]. A systematic review shows that ESWT is not recommended for the treatment of SS[14]. In another study, conducted to assess whether a focused ESWT session was effective in the treatment of military students with chronic shin splint, the control, and treatment groups were both performed the same exercises. According to this study, single-session focused ESWT therapy has been shown to accelerate clinical and functional recovery when combined with a specific exercise program[15]. Similar to our study, they used an exercise program for both groups and both groups showed improvement.

Prolotherapy was found to be effective in many overuse injuries such as lateral epicondylosis[16,17], Achilles tendinopathy[16], Osgood-Schlatter disease[16], rotator cuff[18], and hip adductor tendinopathies[16], plantar fasciitis[16,19,20] and patellofemoral pain syndrome[21]. The formation of SS formation is the damage of the tibia where the adhesion site of the posterior lower leg muscles as a result of overuse. In the treatment of prolotherapy, injection is applied to the enthesis where the muscle adheres to the bone[9]. Although the diagnosis of enthesopathy is unclear, prolotherapy has focused on enthesis as a source of chronic low back pain[22]. Therefore, we similarly applied prolotherapy to enthesis in our study. It has also been shown that prolotherapy is effective in the repair of muscle injuries[23]. Similarly, prolotherapy was shown to be beneficial in improving muscle damage and regeneration in this region in our study. It has even been reported that successful results were achieved by the prolotherapy after failed lumbar disc hernia and rotator cuff surgical repair[10,24]. Akpancar et al. were compared the prolotherapy and platelet-rich plasma injections in the treatment of osteochondritis of talus that is also an overuse injury. Both applications had similar significant successful results.[25] These results showed that prolotherapy is a good choice tissue healing, cartilage repair that usually damaged in overuse injuries.

It's shown that the mean rehabilitation period of SS treatment is more than 80 days[4]. Significant improvement was observed in the prolotherapy group within the first 3 weeks of treatment. Our expectation of prolotherapy treatment was to accelerate the healing process. As expected, pain and functional results were improved faster in the prolotherapy group. As we already had the exercise in both groups, we expected both groups to recover in 24 weeks. Both groups were healed at 24 weeks. The faster the recovery of a disease that requiring a long treatment period, such as shin splint, in a priority health group such as military personnel or elite athletes, the more acceptable the treatment is. According to our study, Prolotherapy can be preferred in the treatment of shin splints because of its rapid results. Also, the Prolotherapy application is an easy and inexpensive method.

CONCLUSION

We could not reach any literature about prolotherapy in the shin splint treatment. It is important that this is the first study on this subject. Further studies are needed with larger patient groups and comparing with different treatment methods to prolotherapy in the treatment of shin splints.

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Author contributions: Conception, Design of the study: [SA, MMS]; Writing: [SA, AO, IS]; Investigation, Data collection: [SA, MMS, AO, IS]

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ORIGINAL RESEARCH

Comparing the Effectiveness of Chiropractic Manipulation and Muscle Energy Technique in Sacroiliac Joint Dysfunction Treatment

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Abstract

Objective: The effects of chiropractic manipulation, muscle energy technique and home exercise program on pain, depression and functional level were compared in patients diagnosed with sacroiliac joint dysfunction (SIJD) in this study.

Material-Method: Forty-five volunteer patients aged 20-65 years who were diagnosed with SIJD participated in this study. The patients were tested through chiropractic and orthopedic examination methods, and aspects of dysfunction were detected. Patients were randomized into 3 groups: Chiropractic Manipulation Group (CM), Muscle Energy Technique Group (MET), Control Group. All groups were assigned a home exercise program. All treatment groups were evaluated with numerical pain scale (NPS), Oswestry low back pain disability questionnaire (OLBPDQ), Beck depression inventory (BDI) and algometer before and after treatment. Descriptive statistics were used in data analysis, Kruskal-Wallis tests in intergroup comparisons, Mann-Whitney U tests in pairwise comparisons, and Friedman, post-hoc Wilcoxon Rank tests were used for intragroup comparisons. The statistical significance value was set at $p<0.05$ in the study.

Results: Of the 45 volunteers who continued the study, 27 were female and 18 were male, and their mean age was 39.47±9.92 years. According to the results of intragroup analyses, a significant difference was found in all examination methods, and as a result of the intergroup analyses, there was a significant difference in all examination parameters except BDI. In the paired comparisons, positive results were obtained in all examinations in the CM and MET groups compared to the control group, in all parameters except for BDI in the analyses between CM and MET, and in examinations performed after the 4-week implementation in favor of CM ($p<0.05$).

Conclusion: In patients with SIJD, CM performed in addition to exercises was found to be more effective than MET and exercise alone.

Keywords: Chiropractic, Muscle Energy Technique, Exercise, Sacroiliac, Dysfunction

INTRODUCTION

Sacroiliac joint dysfunction (SIJD) can be seen in 15-25% of patients with low back pain and in 75% of individuals with lumbar disc herniation. The prevalence of SIJD ranges from 13.8% to 47.9% in the general population [1,2,3]. A dysfunction occurs due to the absence of any pathology in the sacroiliac joint and a biomechanical disorder in the load distribution transferred by the joint to the lower extremity. As a result of this dysfunction, low back and hip pain is frequently observed [4].

According to the guide published by the World Health Organization, chiropractic is an area of specialization that provides the diagnosis, treatment and prevention of diseases of the neuromusculoskeletal system, adjusts the pathological joint biomechanics on the normal joint that is not dislocated or fractured, and applies manual techniques that fall under this field. There are approximately 200 techniques and methods in chiropractic that are similar to or slightly different from each other. Commonly used methods: Methods such as diversified technique, activator method, Cox flexion/extension method, Thompson Drop table method are used [5].

In the study Zelle et al. conducted, chiropractic manipulation (CM) was applied 3 times a week for

2 weeks in volunteers with SIJD. Improvement was observed in most of the patients in the joint movement, pain and Oswestry rating scale [6].

Muscle energy techniques (METs) evolved in osteopathic medicine based on a variety of sources, including the pioneering work of TJ Ruddy (1961). Ruddy's approach (rapid resistive duction) was described as a "muscular energy technique". The core concepts of MET involve using the intrinsic strength of the muscles to achieve a variety of effects that include isometric and isotonic contraction variations. Reducing the tone of the agonist muscle after isometric contraction can also be defined as a form of mobilization of the soft tissue or joint. This technique is accepted as a manual therapy technique [7,8,9]. Kanchan et al. concluded that METs are moderately effective in the treatment of SIJD compared to the Maitland mobilization technique [10].

In general, the treatment of SIJD includes such treatment methods as CM, MET, exercise programs, mobilization methods and conventional therapies. However, the number of studies comparing the efficacy of these treatment methods and the level of evidence are limited. In addition, CM and MET methods have not been compared before in the literature. Therefore, the aim of our study is to compare the effects of CM and MET applied in addition to home exercise program on pain, depression and functional level in patients diagnosed with SIJD.

MATERIALS AND METHODS

This study is a randomized controlled study with three parallel groups. Diagnosed with SIJD, 45 volunteer patients aged between 20-65 who applied to İzmir Katip Çelebi University (İKÇU) Atatürk Training and Research Hospital Physical Therapy Outpatient Clinic participated in the study. Inclusion criteria for the study: Being between the ages of 20-65; having acute pain; having a score of 4 and above on the numerical pain scale (NPS); having a diagnosis of SIJD; volunteering to participate in the study. Non-inclusion criteria: Pregnancy; chronic progressive systemic diseases; malignancy and infectious diseases; history of spinal surgery; severe physical and psychological disorders; congenital hip dislocation; orthopedic and neurological deficits of the lower extremity; inflammatory rheumatological diseases; inflammatory sacroiliitis; surgery, injection, and other similar treatments on the sacroiliac joint in the last 3 months. Exclusion criteria: Unwillingness to continue the study, application of a treatment outside the study protocol, acute fractures of the spine and lower extremity, and becoming pregnant during the study.

Research procedure

In the literature, there are many studies on the effectiveness of CM, which have been performed bidirectionally as well as unidirectionally. In our study, a bidirectional study protocol was adopted and equality in the numbers of patients diagnosed with right or left SIJD was achieved in all groups. Patients diagnosed with SIJD were tested with chiropractic and orthopedic examination methods, and aspects of dysfunction were detected. Then, the volunteer patients were randomly divided into 3 groups as Chiropractic Manipulation group (CM, n: 15; 9 females, 6 males), Muscle Energy Technique group (MET, n: 15; 9 females, 6 males) and Control group (CG, n:15; 9 females, 6 males). After the groups were assigned, the hours and schedules of the procedures related to the treatment and examination of the patients were determined. Homogeneity was evaluated by analyzing the demographic data of the individuals participating in this study. The study, which had initially been designed with 51 people, was completed with 45 people after 6 people were excluded because they did not meet the specified criteria. Applications and examinations were performed by a physiotherapist with 2 years of experience and a master's degree, and a specialist physician who attended the courses.

In order to determine the sample size of the study, power analysis was performed using the G*Power (v3.1.9.2) program. The power of the study was found to be 1-β (β = probability of type II error). In the calculation performed to obtain 95% power at the α=0.05 level based on the pain (VAS), mean, and standard deviation values in Kamali and Shokri's (2012) study (initial value in patients with SIJD in whom high-velocity low-amplitude manipulation technique was applied: 41.56±21.03 / that after 1 month: 9.00±12.27), the effect size (d) was found to be 1.779. In the same study, the effect size (d) was found to be 1.866 in the calculation made to obtain 95% power at the α=0.05 level based on the changes in the scores of the Oswestry Low Back Pain Disability Questionnaire (OLBPDQ) (initial score: 24.58±8.83 / that after 1 month: 8.62±8.24) in the patient group with SIJD [29.] Accordingly, it was determined that there should be at least 6 people in each group. The study was planned on a total of 45 patients, 15 participants for

each group. In the home exercise program, it was aimed to provide mobility in the sacroiliac joint, pelvic stabilization, strengthening of the low back and hip muscles, and stretching of the shortened muscles. The exercises were explained to the patient in detail, and they were asked to perform at least 10 repetitions, 3 times a day every day [30].

CM was performed with the diversified technique in the side lying position. By evaluating the patient's leg length, high-velocity low-amplitude CM was applied to the sacroiliac joint in the anterior superior or posterior inferior direction [31].

MET, on the other hand, was performed with 10 repetitions in the supine and prone positions using long and short lever arms [32].

Only ergonomic adjustments and home exercise program were assigned to the control group. In the CM group, in addition to ergonomic adjustments and home exercise program, CM was applied twice for 4 weeks. In the MET group, in addition to ergonomic adjustments and home exercise program, MET was applied twice for 4 weeks. Examinations were performed using NPS, Beck Depression Inventory (BDI), OLBPDQ and Baseline 30 algometer (dolorimeter) device before the treatment and at the second and fourth weeks after the treatment.

Chiropractic manipulation

Diverse field chiropractic technique was used in our study. CM was performed 2 times a week for 4 weeks.

After evaluating the patient with the Derifield Leg Check test, the chiropractic manipulation direction and contact point were selected according to the position of the sacroiliac joint. The patient was asked to tie his arms while he was in the side lying position. Pushing maneuver was performed with HVLA from posterior to anterior and from medial to lateral with pelvic rotation. The contact point of the sacroiliac joint was PSIS.

Muscular energy technique

In muscle energy technique, it was used in combination with 4 different techniques: long and short leverage, distraction, and combined isometric method. MET was performed 2 times a week for 4 weeks. During each application, the patient's isometric contraction of 3-5 seconds was provided and repeated 10 times. In the long and short lever, distraction technique, the patient is in the supine position and the practitioner is on the dysfunction side. In the combined isometric technique, the patient is in the prone position and the practitioner is on the dysfunction side.

Ergonomic arrangements and home exercise program

Ergonomic arrangements were given to all patient groups in the form of a form and explained in detail. It was aimed to reduce such problems to a great extent by giving training on the correct use of movements that are repeated many times in daily life.

All exercises were requested to be performed for both lower extremities. Theraband in green color was recommended for exercises performed with resistance. A program that combined lumbar region muscle strengthening, back extensors stretching, hip flexors and extensors stretching, hip flexors and extensors strengthening, bridge exercise was applied. It was requested that the exercise program be performed every day, 3 times a day, at least 10 repetitions.

Primary outcome measures

The diagnosis and differentiation of SIJD as the primary outcome measure was evaluated with 7 orthopedic tests consisting of Gillet [33], Standing Flexion [33], Prone Extension [34], Compression [35], Gaenslen [35], Yeoman's [33] and Faber [35]. Diversified leg check was used to determine the method of CM [36].

Numerical pain scale (NPS)

The NPS is an 11-point rating scale ranging between 0-10, with the phrase “no pain” on the far left and “worst pain imaginable” on the far right. The current, best and worst pain levels of the patients in the last 24 hours are evaluated [37].

Oswestry low back pain disability questionnaire (OLBPDQ)

The OLBPDQ has become one of the condition-specific outcome measures used in the treatment of spinal disorders [40]. It is a self-administered questionnaire divided into ten sections designed to assess the limitations of various activities of daily living. Each section is scored between 0-5 and a score greater than 5 represents a disability. The questionnaire is calculated by dividing the total score by the total possible score, which is then multiplied by 100 and expressed as a percentage. Thus, the denominator is reduced by 5 for each unanswered question. If a patient ticks more than one statement in a question, the one with the highest score is recorded as a true disability indicator [41].

Pressure pain threshold measurement (PPT)

Pressure pain threshold measurement is an objective tool used to measure pain sensitivity. The

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instrument designed for this purpose is called the algometer. While the patient is in the prone position, the therapist applies an axial force to assess the tenderness of the Posterior Superior Iliac Spine (PSIS) as a whole, placing the probe of the algometer 1 cm below the PSIS. Patients are asked to report the first pain they perceive when force is applied to them. This procedure was repeated three times with 1-minute intervals between each trial, and the mean was considered the final score. Force measurements were recorded in kilograms [38].

Secondary outcome measures

Beck depression inventory (BDI)

The BDI is a 21-item self-report questionnaire aiming to assess the severity of depression in normal and psychiatric populations. It was developed by Beck et al. in 1961. It is based on the theory of negative cognitive distortions that are central to depression [39.] Simple random sampling method was used for patients. To this end, the sampling module on the computers was used. In addition, attention was paid to the distribution of patients into the groups based on their gender.

Permissions

The study was designed in accordance with the Declaration of Helsinki, and approval was obtained from the Izmir Katip Çelebi University Faculty of Medicine Clinical Research Ethics Committee on 17.05.2018. Photos were shot following the approval of the participants, and permissions were obtained for the photos to be shared.

Statistical analysis

BDI, NPS, OLBPDQ and algometer measurements were performed before the treatment, 2 weeks and 4 weeks after the treatment of the groups, which were divided into CM group, MET group and control group. It was examined whether these examinations differed both by time within the group and at different times between the groups.

Kruskal-Wallis test was used for intergroup comparisons, Mann-Whitney U test for pairwise comparisons, Friedman test for intragroup comparisons, and Wilcoxon Rank test was used for paired comparisons. SPSS 25.0 package program (SPSS Inc., Chicago, IL) was used to evaluate the data within the scope of the study. The statistical significance value was set at $p<0.05$ in the study.

RESULTS

There was no statistically significant difference between the groups in terms of age (p=0.108), height (p=0.117), body weight (p=0.147), body mass index (p=0.646) (p>0.05) (Table 1).

Table 1. Demographic characteristics of patients

Parametreler	Mean ± SD (Min-Max)			Kruskal Wallis H value	df	P value
	CM (n:15)	MET (n:15)	CG (n:15)			
Age (years)	39.47±9.92 (23-56)	35.07±10.06 (19-51)	43.4±10.76 (22-57)	4.46	2	0.108
Height (cm)	168.73±7.61 (158-182)	169.07±10.24 (155-191)	174.33±7.35 (157-187)	4.30	2	0.117
Body weight (kg)	68.4±15.62 (47-96)	69.73±12.59 (49-92)	76±7.48 (59-85)	3.84	2	0.147
Body mass index (kg/m^2)	23.77±3.94 (17.9-29.3)	24.2±2.72 (19.6-29.8)	25.09±3.14 (20.9-31.6)	0.87	2	0.646
Gender (Female/Male) (n)	9/6	9/6	9/6			

*p<0.05; **p<0.01; ***p<0.001* CM: Chiropractic Manipulation, MET: Muscle energy techniques, CG: Control Group

In order to understand whether the treatment results differed according to the measurements carried out at different times within the groups, comparisons were performed within the 3 groups.

There were statistically significant differences between NPS and OLBPDQ in the CM group according to different times (p<0.001). In terms of both parameters, there are statistically significant differences in the combinations between the first measurements, the second measurements performed after the treatment, and the third measurements. NPS scores decreased significantly while OLBPDQ scores increased significantly (Table 2). When the BDI scores of the CM group were examined at different times, there was a statistically significant difference (p<0.001). Statistically significant differences were observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements (p<0.01). The scale scores decreased significantly (Table 2).

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Table 2. Within-group comparisons

Parameters		Mean ± SD (Min-Max) 1.Test	2.Test	3.Test	Chi-Square Value	df	P value	Differences Between Groups
CM	NPS	7.67±0.9 (6-9)	4.2±1.57 (2-8)	1.6±1.06 (0-4)	29.53	2	<0.001***	1.Test>2.Test*** 2.Test>3.Test*** 1.Test>3.Test***
	PPT	4.87±1.4 (3-7.5)	7.43±2.1 (4-14.5)	9.83±2.77 (7.5-18.5)	30.00	2	<0.001***	1.Test<2.Test*** 2.Test<3.Test*** 1.Test<3.Test***
	BDI	26.07±18.3 (4-51)	17.67±13.15 (1-37)	8.93±7.51 (0-26)	19.75	2	<0.001***	1.Test>2.Test** 2.Test>3.Test** 1.Test>3.Test**
	OLBPDQ	46.8±20.04 (22-82)	25.6±14.99 (6-50)	11.33±8.71 (0-28)	21.66	2	<0.001***	1.Test>2.Test** 2.Test>3.Test** 1.Test>3.Test***
MET	NPS	7.4±1.24 (5-10)	4.8±1.15 (3-7)	3±0.65 (2-4)	28.53	2	<0.001***	1.Test>2.Test*** 2.Test>3.Test** 1.Test>3.Test***
	PPT	5.6±2.21 (3.5-13)	7±1.98 (5-13.5)	8.4±2.05 (6.5-15)	29.53	2	<0.001***	1.Test<2.Test*** 2.Test<3.Test*** 1.Test<3. Test***
	BDI	27.87±17.11 (4-47)	21.13±13.82 (2-37)	15.27±10.97 (0-32	29.53	2	<0.001***	1.Test>2.Test*** 2.Test>3.Test*** 1.Test>3.Test***
	OLBPDQ	51.87±24.64 (16-86)	36.27±17.14 (14-68)	24.27±13.37 (4-46)	28.13	2	<0.001***	1.Test>2.Test*** 2.Test>3.Test*** 1.Test>3.Test***
CG	NPS	8±0.93 (7-9)	6.73±1.1 (5-9)	5.8±1.08 (4-8)	26.12	2	<0.001***	1.Test>2.Test** 2.Test>3.Test** 1.Test>3.Test***
	PPT	3.37±1.01 (2-5)	4.1±0.81 (2.5-5)	4.43±0.88 (3-5.5)	23.53	2	<0.001***	1.Test<2.Test** 2.Test<3.Test** 1.Test<3.Test***
	BDI	41.6±8.76 (23-54)	35.53±9.84 (18-53)	28.67±9.88 (11-42)	30.00	2	<0.001***	1.Test>2.Test*** 2.Test>3.Test*** 1.Test>3.Test***
	OLBPDQ	62.73±19.45 (32-88)	52.53±17.49 (24-80)	44.67±18.14 (14-76)	30.00	2	<0.001***	1.Test>2. Test*** 2.Test>3. Test*** 1.Test>3. Test***

*p<0.05; **p<0.01; ***p<0.001* CM: : Chiropractic Manipulation, MET: Muscle energy techniques, CG: Control Group, NPS: Numerical Pain Scale, PPT: Pressure Pain Threshold, BDI: Beck Depression Inventory, OLBPDQ: Oswestry Low Back Pain Disability Questionnaire

OLBPDQ scores displayed a statistically significant difference according to time (p<0.001). Statistically significant differences were observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements (p<0.01; p<0.001). The scale scores decreased significantly (Table 2).

Statistically significant differences were found between the NPS and OLBPDQ scores in the MET group according to different times (p<0.001). Statistically significant differences were observed in both parameters between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements (p<0.01; p<0.001). NPS scores decreased significantly while OLBPDQ scores increased significantly (Table 2).

The BDI scores of the MET group showed a statistically significant difference according to different times (p<0.001). Statistically significant differences were observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements (p<0.001). The scale scores decreased significantly (Table 2).

The OLBPDQ scores of the MET group displayed a statistically significant difference according to time (p<0.001). Statistically significant differences were

observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements ($p<0.01$). The scale scores decreased significantly (Table 2).

Statistically significant differences were found between the NPS and OLBPDQ scores of CG according to different times ($p<0.001$). In terms of both parameters, there were statistically significant differences in the combinations between the first measurements, the second measurements following the treatment, and the third measurements ($p<0.01$; $p<0.001$). The NPS scores decreased significantly, while OLBPDQ parameters increased significantly (Table 2).

The BDI scores of CG showed a statistically significant difference according to different times ($p<0.001$). Statistically significant differences were observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements ($p<0.01$). The scale scores decreased significantly (Table 2).

In CG, the OLBPDQ scores indicated a statistically significant difference according to time ($p<0.001$). Statistically significant differences were observed in the scale scores between the combinations of the first measurements, the second measurements performed after the treatment, and the third measurements ($p<0.01$). The scale scores decreased significantly (Table 2).

In order to understand whether the measurement parameters differed according to the groups, tests in which the 3 groups were compared together were performed.

There was no statistically significant difference between the groups in terms of the first NPS measurement ($p>0.05$). However, significant differences were observed in terms of the second and third measurements ($p<0.001$). In the second measurement, the NPS scores in CG were statistically significantly higher than those in the CM and MET groups ($p<0.001$). In the third measurement, the NPS score in CG was statistically significantly higher than those in the CM and MET groups, and the NPS score in the MET group was statistically significantly higher than that in the CM group ($p<0.001$) (Table 3).

There were statistically significant differences between the groups in terms of the first, second and third measurements of the OLBPDQ parameter ($p<0.001$). The treatment groups were statistically significantly higher than the CG in the first and second measurements, ($p<0.01$; $p<0.001$). In the third measurement, the treatment groups were statistically significantly higher than CG ($p<0.001$), and the score of the CM group was statistically significantly higher than that of the MET group ($p<0.05$) (Table 3).

There were statistically significant differences between the groups in terms of the first, second and third measurements of the BDI score ($p<0.05$; $p<0.001$). In all measurements, the scores of CG were statistically significantly higher than the scores of CM and MET groups ($p<0.05$; $p<0.01$; $p<0.001$) (Table 3).

There was no statistically significant difference between the groups in terms of the first measurement of OLBPDQ score ($p>0.05$). There were significant differences in terms of the 2nd and 3rd measurements ($p<0.001$). In the second measurement, the OLBPDQ score of the CG was statistically significantly higher than the CM and MET groups ($p<0.05$; $p<0.001$). In the third measurement, both the OLBPDQ score of the CG was statistically significantly higher than the CM and MET groups, and the OLBPDQ score of the MET group was statistically significantly higher than the CM group ($p<0.01$) (Table 3).

DISCUSSION

In this study, the effectiveness of CM and MET methods applied for 4 weeks in patients diagnosed with SIJD were compared. The diagnosed patients were randomly selected and divided into three groups, namely CM, MET and CG. Ergonomic arrangements and home exercise program were assigned to all groups.

In a case study conducted by Boyle et al., an acceptable improvement was observed in the NPS and OLBPDQ scores when an exercise program was applied to a 65-year-old female patient diagnosed with SIJD [11]. The study Jeong-Hyun et al. conducted showed that functional training and mobilization increased static stability and reduced pain in 20-year-old university students with SIJD [12]. In our study, similar treatment and test methods were used, and the age range was similar, which was determined to be 20 to 65 years.

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Tablo 3. Decoupling between groups

Parameters		Mean. ± SD (Min-Max)			Kruskal Wallis H value	df	P value	Differences Between Groups
		CM (n=15)	MET (n=15)	CG (n=15)				
NPS	1.TEST	7.67±0.9 (6-9)	7.4±1.24 (5-10)	8±0.93 (7-9)	2.25	2	0.325	
	2.TEST	4.2±1.57 (2-8)	4.8±1.15 (3-7)	6.73±1.1 (5-9)	19.81	2	<0.001***	CG>CM*** CG>MET***
	3.TEST	1.6±1.06 (0-4)	3±0.65 (2-4)	5.8±1.08 (4-8)	35.02	2	<0.001***	MET>CM*** CG>CM*** CG>MET***
PPT	1.TEST	4.87±1.34 (3-7.5)	5.6±2.21 (3.5-13)	3.37±1.01 (2-5)	16.49	2	<0.001***	CM>CG** MET>CG***
	2.TEST	7.43±2.51 (4-14.5)	7±1.98 (5-13.5)	4.1±0.81 (2.5-5)	25.97	2	<0.001***	CM>CG*** MET>CG***
	3.TEST	9.83±2.77 (7.5-18.5)	8.4±2.05 (6.5-15)	4.43±0.88 (3-5.5)	31.54	2	<0.001***	CM> MET* CM>CG*** MET>CG***
BDI	1.TEST	26.07±18.3 (4-51)	27.87±17.11 (4-47)	41.6±8.76 (23-54)	6.10	2	<0.001***	CG>CM* CG>MET*
	2.TEST	17.67±13.15 (1-37)	21.13±13.82 (2-37)	35.53±9.84 (18-53)	13.95	2	<0.001***	CG>CM*** CG>CET**
	3.TEST	8.93±7.51 (0-26)	15.27±10.97 (0-32)	28.67±9.88 (11-42)	18.57	2	<0.001***	CG>CM*** CG>MET**
OLBPDQ	1.TEST	46.8±20.04 (22-82)	51.87±24.64 (16-86)	62.73±19.45 (32-88)	4.35	2	0.113	
	2.TEST	25.6±14.99 (6-50)	36.27±17.14 (14-68)	52.53±17.49 (24-80)	14.6	2	<0.001***	CG>CM*** CG>MET*
	3.TEST	11.33±8.71 (0-28)	24.27±13.37 (4-46)	44.67±18.14 (14-76)	22.01	2	<0.001***	MET>CM** CG>CM*** CG>MET**

*p<0.05; **p<0.01; ***p<0.001* CM: : Chiropractic Manipulation, MET: Muscle energy techniques, CG: Control Group, NPS: Numerical Pain Scale, PPT: Pressure Pain Threshold, BDI: Beck Depression Inventory, OLBPDQ: Oswestry Low Back Pain Disability Questionnaire

The study by Walker et al. showed that CM is effective in pain and dysfunction in the lower back and hip [13]. In their study conducted with 30 volunteers, Childs et al. reported significant changes in NPS and OLBPDQ scores as a result of CM in patients with acute and chronic low back pain and asymmetry in the pelvis region [14]. Zelle et al. applied CM 3 times a week for 2 weeks in 11 volunteers with SIJD in their study. Most patients showed improvement in joint motion, pain, and the Oswestry rating scale [6]. Suter et al. revealed that sacroiliac joint manipulation led to a decrease in lower extremity muscle inhibition in patients with SIJD and knee complaints [15]. Similarly, positive effects were obtained in our study in terms of NPS, PPT, OLBPDQ and BDI scores in the study group, where CM was performed twice a week for 4 weeks in addition to ergonomic arrangements and home exercise program. These results are in accordance with the literature.

Heinzman concluded that MET could be an effective treatment for acute injuries and sports injuries, chronic pain, hypertonicity and muscle spasms [16]. Kanchan et al. concluded that METs are moderately effective in the treatment of SIJD compared to the Maitland mobilization technique. The results of the study showed that MET combined with active exercises was moderately significant in improving functional ability compared to Maitland mobilization technique [10]. A moderate improvement was observed in our study in the NPS, PPT, OLBPDQ and BDI scores in the group in which MET was applied twice for 4 weeks in addition to ergonomic adjustments and home exercise program, compared to CM. This result is similar to the results of Kanchan et al.

Sai Kumar et al. concluded that the exercise applied to the adductor muscle groups together with traditional exercise for 2 weeks had a positive effect on the improvement of pain and functional status in patients with SIJD [17]. In the study by Added et al., an exercise program aimed at the gluteus maximus

muscle was applied in patients with SIJD. There was a decrease in pain, and all subjects were discharged from physical therapy and were able to return to their normal daily activities [18]. Michael et al. carried out a study examining the effects of postural exercises on sacroiliac joint pain and found a significant improvement in pain [19]. In our study, exercises aimed at stretching and strengthening the muscles especially in the low back and hip regions were applied to patients with SIJD. In the analyzes performed at the end of four weeks, positive results in terms of NPS, PPT, OLBPDQ and BDI scores were revealed in CG, which is consistent with the literature.

The review Al Subahi et al. conducted revealed that manipulation is the most effective and common approach in reducing pain and problems associated with SIJD, and it is used in physical therapy clinics. They showed that manipulation is more effective than other treatment approaches in the treatment of pain and pelvic asymmetry in SIJD [20]. In the literature review we conducted, we observed that CM and MET had not been compared before. When we compared CM and MET in our study, our results were in favor of CM in terms of NPS, OLBPDQ and PPT scores. In the study Barbosa et al. conducted, pain reduction and functional improvement were reported in patients with SIJD when spinal manipulation and isotonic exercise program were used, and they found that spinal manipulation method was more successful than exercise program [21]. Similar to the study by Barbosa et al., positive results were obtained even in terms of NPS, PPT, OLBPDQ and BDI scores compared to the group in which only ergonomic adjustments and home exercise program of CM were applied. Fernandez et al. studied the effects on psychological, analgesic and segmental inhibitory mechanisms after spinal manipulation [22]. As in the study by Fernandez et al., better results were obtained compared to the other treatment groups.

Giles et al. concluded that there is a strong correlation between leg length disparity and low back pain lasting at least 3 months. The study revealed that this significant leg disparity could be corrected and it was improved nearly back to normal in people who underwent MET compared to those who received conventional therapy [23]. In the study by Mathew et al., MET and mobilization techniques were compared with the conventional therapy method. MET and mobilization techniques were shown to be more successful than conventional therapy in NPS and modified Oswestry low back pain disability scores [24]. It was found in our study that MET which was applied in addition to ergonomic regulations and home exercise program helped obtain better results in terms of NPS, PPT, OLBPDQ scores compared to the group that only did exercises, and this finding is in accordance with the literature.

In the study by Robertson et al., it was found that low back pain experienced by more than 50% of the subjects was significantly associated with both depression and somatization [25]. In the study Kennedy et al. conducted with 973 university students, it was shown that psychological factors are directly related to the prevalence of low back pain [26]. Similarly, in their study on 250 university students, Ünalan et al. revealed the relationship between back pain and depression [27]. On the other hand, Mitchell et al., in their study on 170 nursing students, found that there was no difference in the depression scores between the group with and without low back pain [28]. In light of this information, the level of depression in the patients diagnosed with SIJD was examined in our study, and BDI was used to test it. In addition, it was aimed to reveal how much the treatment could be effective if the patient has a high level of depression. When the treatment groups were compared, it was observed that the scores obtained in the CM and MET groups in the second and third measurements following the treatment revealed more significant results compared to the CG. When the scores of the CM and MET groups were compared, it was found that there was no significant difference between them.

Limitations of the study

The fact that the exercises given in the treatment protocol we applied were not performed with a physiotherapist and that the treatment program was completed in a short period of time, i.e. 4 weeks, are among the limitations of our study.

CONCLUSION

As a result of our study, an improvement was observed in pain, pressure pain threshold, functional and depression levels in patients with SIJD when the home exercise program was compared with the pre- and post-treatment of CM and MET applied in addition to the home exercise program. It was concluded that CM applied in addition to the home exercise program was more successful in terms of pain, pressure pain threshold and functional levels

compared to the other treatment methods. It was found that MET applied in addition to the home exercise program was more successful in terms of pain, pressure pain threshold and functional levels compared to the home exercise program alone. It was found that the CM and MET applied in addition to the home exercise program led to a greater decrease in the depression level than the home exercise program alone. However, no difference was found between CM and MET applied in addition to the home exercise program in reducing the level of depression.

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ORIGINAL RESEARCH

Evaluation of the Knowledge, Attitudes and Behaviors of Midwives and Nurses about Traditional and Complementary Treatment Methods

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Abstract

Objective: This research aims to determine the knowledge, attitudes, and behaviours of midwives and nurses with regard to traditional and complementary treatment methods.

Material-Method: This descriptive, cross-sectional study was carried out between May and August 2021 with the participation of 248 midwives and nurses working in a District Health Directorate in the Mediterranean Region. A questionnaire about the knowledge and opinions of midwives and nurses with regard to traditional and complementary medicine, prepared by the researchers by reviewing the literature, and the Attitudes towards Holistic Complementary and Alternative Medicine Scale were used to collect the study data. In the comparison of quantitative data, the Student-t testi and Mann-Whitney U test was used in the case of two groups, and the Oneway Anova and Kruskal-Wallis test was used for more than two groups. Also, Pearson Korelasyon Coefficient was used to evaluate the linear relationship between two numerical measurements.

Results: In order to prevent the unconscious use of Complementary and Alternative Medicine methods among the public, it is important for midwives and nurses to have sufficient knowledge about these methods and to investigate their level of knowledge**.** The Scale mean score of the midwives and nurses was determined as 26.86±7.46. The negative, weak correlation between the ages of the participants and their Complementary and Alternative Medicine sub-dimension score was found to be statistically significant (p=0,001; p<0,01). The negative, weak correlation between the ages of the participants and their Holistic Health sub-dimension score was found to be statistically significant (p=0,022; p<0,05).

Conclusion: Although the midwives and nurses lacked knowledge about Traditional and Complementary Medicine methods, their attitudes were positive and they were willing to receive training. All midwives and nurses interested in or practicing CAM should be strengthened in this field in order to gain necessary skills by participating in training programs.

Keywords: Traditional and Complementary Medicine, Midwife, Nurse.

INTRODUCTION

Traditional and Complementary Medicine (TCM) involves all historical health care practices, techniques and methods, and the related knowledge, beliefs, and social experiences, that differ from the current healthcare system[1]..Throughout history, humanity has had to struggle with many diseases and has tried to find ways of treating these diseases with inherited techniques that use materials obtained from nature. Traditional treatment methods emerged as a result of the search for health care solutions that can be applied in various cultural contexts and with regard to different religious beliefs, philosophies, and experience[2].The World Health Organization (WHO) has defined traditional medicine practices as “the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness"[3,4]. In the TCM regulations published by the Ministry of Health in Türkiye in 2014, fourteen traditional and complementary medicine methods were defined for the first time[5]. These methods were apitherapy, phytotherapy, hypnosis, homeopathy, leech therapy, chiropraxis, cupping, larva therapy, mesotherapy, prolotherapy, osteopathy, ozone therapy, reflexology, and music therapy[6,7].

TCM methods are methods used to support conventional treatment. The main purpose of using these methods is to improve quality of life and reduce symptoms. Also, It is stated that the use of complementary therapy provides holistic care and the opportunity to respond to the wishes and needs of the society. However, in terms of patient safety and the need to provide quality services with a holistic approach, and in order for these methods to attain their goals, it is important that healthcare professionals are knowledgeable about these practices, that they are able to prevent any potential harm to or abuse of patients, and that they choose evidence-based techniques[8-11]. So, adding evidence-based complementary and integrated practices to midwifery and nursing curriculum, developing nursing practices related to these techniques and determining effective strategies are very important in terms of advising patients and their relatives about these methods[11-13]. In this regard, it is vital that views of midwives and nurses about complementary and alternative treatments be determined. This study thus aimed to determine the knowledge, attitudes, and behaviors of midwives and nurses working in a district of the Mediterranean region with regard to traditional and complementary treatment methods.

MATERIALS AND METHODS

Study design

This study had a cross-sectional, descriptive design.

Participants and setting

A total of 266 midwives and nurses working in a district in the Mediterranean Region constituted the universe of the study. Sample selection was not conducted in the research. The study was conducted between May and August 2021 with 248 midwives and nurses who agreed to participate. Inclusion criteria of the study consists of individuals (a) worked as midwives and nurses, (b) who filled in all scales, and (h) who have agreed to participate in the research. The data were collected face to face, following the rules of social distance and mask. The questionnaires were filled by the participants in an average of 5-10 minutes.

Outcome measurement tools

An Information Form (15 questions) prepared by the researchers after reviewing the literature[5,7-10] and the Attitudes towards Holistic Complementary and Alternative Medicine Scale (AHCAMS) (11 items) were used to collect study data. The study was conducted in accordance with principles of the Declaration of Helsinki.

Attitudes towards holistic complementary and alternative medicine scale [AHCAMS]

This scale was developed by Hyland et al[14]. in 2003 and its Turkish validity and reliability study was carried out by Erci[15]. The scale, which determines attitudes towards complementary and alternative medicine, consists of 11 items in a 6-point Likert-type scale. The scale has two sub-dimensions, Complementary and Alternative Medicine (CAM) and Holistic Health. The lowest score that can be obtained from the scale is 11, and the highest score is 66. As the score of the scale decreases, positive attitudes towards complementary and alternative medicine increase. The Cronbach alpha reliability coefficient of the scale is 0.72[15]. In our study, the cronbach alpha value was found 0.77.

Statistical analysis

Statistical analysis was performed using the Number Cruncher Statistical System (NCSS) 2007 (Kaysville, Utah, USA) software. Descriptive statistical methods (mean, standard deviation, median, frequency, percentage, minimum, maximum) were used to analyze the study data. In the comparison of quantitative data, the Student-t testi and Mann-Whitney U test was used in the case of two groups, and the Oneway Anova and Kruskal-Wallis test was used for more than two groups. Also, Pearson Korelasyon Coefficient was used to evaluate the linear relationship between two numerical measurements. The results were evaluated at the 95% confidence interval and at a significance level of $p<0.05$.

Ethical considerations

In order to conduct the study, ethical approval (Date: 02.12.2020; Decision No: GO 2020/317) was obtained from the Non-Interventional Clinical Research Ethics Committee of the university involved. Written and verbal consent was obtained from all those participating in the study.

Limitations

There are few limitations to our review. Our sample only represents individuals with nursing and midwife. The findings will not be generalizable to other health professional. Also, because our study was conducted in a center, the results of the study can only be generalized to the place where the study was conducted**.**

RESULTS

The ages of the participants ranged from 19 to 62, with a mean age of 37.95±10.27 years. Among the participants, 41.1% (n=102) were midwives and 58.9% (n=146) were nurses. In terms of education

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level, 71.4% of the participants were university graduates, while 14.5% were high school graduates only. 77.4% of the participants were married and 19.4% had a chronic disease. Among those with chronic diseases, 35.4% had hypertension, 20.8% had diabetes, and 12.5% had allergic asthma (Table 1).

Table 1. Distribution of sociodemographic characteristics (n= 248)

Age	*Mean±SD*	37.95±10.27
		n (%)
Profession	Midwife	102 (41.1)
	Nurse	146 (58.9)
Educational degree	High school graduate	36 (14.5)
	University graduate (Associate degree)	27 (10.9)
	University graduate (Bachelor's degree)	177 (71.4)
	Master's graduate	7 (2.8)
	PhD graduate	1 (0.4)
Marriage	Single	45 (18.2)
	Married	192 (77.4)
	Divorced and widowed	11 (4.4)
Chronic disease	No	200 (80.6)
	Yes	48 (19.4)
	Hypertension	17 (35.4)
	Diabetes	10 (20.8)
	Allergic asthma	6 (12.5)
	Others*	15 (32.3)

* ulcerative colitis (3-6.3), cardiac insufficiency (2-4.2), Familial Mediterranean Fever (2-4.2), panic attack (2-4.2), thyroid cancer (2-4.2), essential thrombocytosis (1-2.1), kidney failure (1-2.1), Ankylosing spondylitis (1-2.1), gastric cancer (1-2.1).

While 96.4% of the participants had heard of TCM treatment, only 5.6% had received TCM training; 84.3% wanted to receive TCM training. In terms of reasons for using TCM, 46.4% of the participants used it for treatment, 9.7% for pain relief, and 1.6% for prevention. 19% of the participants believed that the most effective treatment method was conventional medicine, 0.4% believed that it was TCM alone, and 80.6% believed that the most effective treatment was conventional medicine combined with TCM. 63.3% of the participants were keen to try out TCM. While the percentage of midwives and nurses using TCM was 49.2%, 69% of their patients used it. When the knowledge of the participants about TCM methods was examined, it was determined that 75.4% knew about ozone therapy, 73.8% knew about leech therapy, and 73.4% knew about cupping therapy (Table 2, Figure 1).

Table 2. Distribution of questions regarding CAM (n=248)

		n (%)
Have you heard of CAM?	Yes	239 (96.4)
	No	9 (3.6)
Have you received CAM training?	Yes	14 (5.6)
	No	234 (94.4)
Would you like to receive CAM training?	Yes	209 (84.3)
	No	39 (15.7)
Should CAM be used in patient care?	Yes	209 (84.3)
	No	39 (15.7)
Have you ever used CAM?	Yes	122 (49.2)
	No	126 (50.8)
Have your patients used CAM?	Yes	171 (69.0)
	No	77 (31.0)
Reason for using CAM (n=143)*	Treatment	115 (80.4)
	Relaxation	24 (17.8)
	Protection	4 (2.8)
What do you think is the most effective treatment method?	Medical	47 (19.0)
	CAM	1 (0.4)
	Medical with CAM	200 (80.6)
Status of wanting to apply CAM	Yes	157 (63.3)
	No	91 (36.7)

The scores obtained from the CAM sub-dimension ranged from 6 to 27, with a mean of 15.91±4.60 and α=0.609. The scores obtained from the Holistic Health sub-dimension ranged from 5 to 27, with a mean of 10.94±4.32 and α=0.846. The scores obtained from the total AHCAMS ranged from 11 to 47, with a mean of 26.86±7.46 and α=0.771 (Table 3).

Table 3. Attitudes towards holistic complementary and alternative medicine scale significance (n=248)

	Number of items	**Mean±SD**	**Median (Min-Max)**	**Cronbach's Alpha**
Complementary and Alternative Medicine	6	15.91±4.60	15.5 (6-27)	0.609
Holistic health	5	10.94±4.32	11 (5-27)	0.846
Total	11	26.86±7.46	27 (11-47)	0.771

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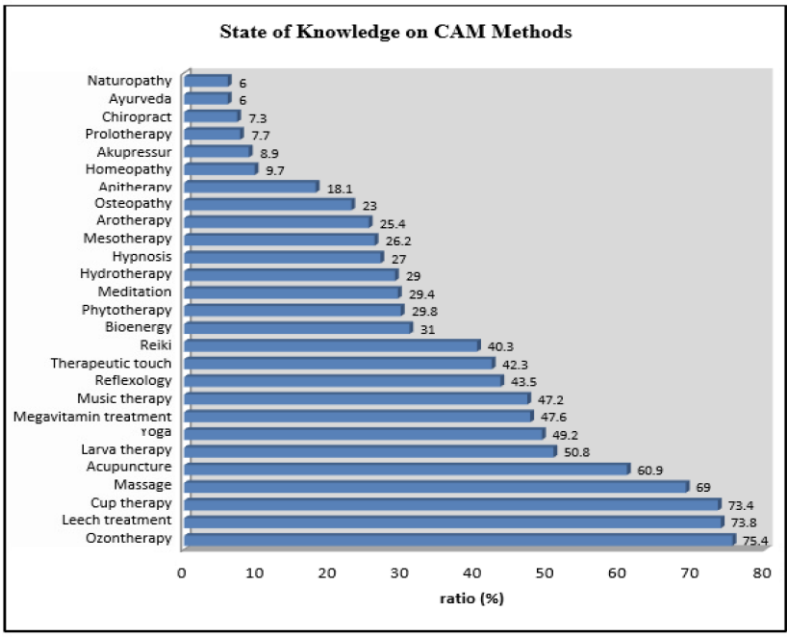

Figure 1. Distribution of knowledge levels on CAM Methods

The negative, weak correlation between the ages of the participants and their CAM sub-dimension score was found to be statistically significant. The negative, weak correlation between the ages of the participants and their Holistic Health sub-dimension score was found to be statistically significant. The negative, weak correlation between the ages of the participants and their total AHCAMS score was found to be statistically significant. The scores of the participants who were nurses for the CAM sub-dimension and the total scale were found to be statistically significantly higher than the scores of the participants who were midwives. The Holistic Health sub-dimension scores and the total scale scores of the participants with a chronic disease were found to be statistically significantly higher than the participants without a chronic disease ($p<0.05$) (Table 4).

Table 4. Evaluation of socio-demographic characteristics according to the attitude scale to integrative complementary and alternative medicine (n= 248)

			Complementary Alternative Medicine	**Holistic health**	**HCAMQ Total score**
Age (year)		r	-0.209ǂ	-0.145ǂ	-0.220ǂ
		p	0.001**	0.022*	0.001**
Marriage	Single (n=45)	Mean±SD	16.82±4.28	12.02±5.33	28.84±7.4
	Married (n=192)	Mean±SD	15.76±4.44	10.63±3.89	26.39±6.93
	Divorced and widowed (n=11)	Mean±SD	15±7.85	12.09±6.2	27.09±13.97
		p	[a]0.211	[a]0.207	[a]0,105
Education degree	High school graduate (n=36)	Mean±SD	15.44±4.23	11.89±3.65	27.33±7.25
	University graduate (Associate degree) (n=27)	Mean±SD	15.89±3.47	10.81±3.27	26.7±5.85
	Undergraduate and above graduate (n=185)	Mean±SD	16.02±4.83	10.78±4.56	26.8±7.74
		p	[b]0,772	[a]0.105	[b]0.920
Profession	Midwife (n=102)	Mean±SD	14.07±4.58	9.17±3.02	23.24±6.59
	Nurse (n=146)	Mean±SD	17.21±4.17	12.19±4.66	29.4±6.99
		p	[c]0,001**	[d]0.086	[c]0.001**
Chronic disease	None (n=200)	Mean±SD	15.6±5.05	8.9±2.7	24.5±6.65
	Yes (n=48)	Mean±SD	16±4.5	11.44±4.5	27.44±7.55
		p	[c]0.598	[d]0.001**	[c]0.014*

*[a]Kruskal Wallis Test, [b]Oneway Anova Test, [c]Student t-Test, [d]Mann-Whitney U Test, ǂPearson Korelasyon Coefficient, *p<0,05, **p<0,01*

DISCUSSION

While individuals' quality of life and average life expectancy have increased as a result of the benefits of modern conventional medicine, the rates of specific, chronic and fatal diseases are increasing. This situation has caused patients, their relatives, and healthcare professionals to seek different solutions, and the use of TCM methods has thus become widespread[16]. This study examined the knowledge, attitudes, and behaviours of midwives and nurses with regard to traditional and complementary treatment methods.

It was determined that while almost all of the midwives and nurses had heard of TCM treatment, very few (5.6%) had received TCM training, and a large majority (84.3%) wanted to receive TCM training. 49.2% of the participants currently used TCM. Similar to our study, Kahraman and Kırkan[17] determined that the majority of pediatric nurses had not received any training on TCM practices but were willing to receive training. The study of Bahall and Legal determined that 92.4% of nurses and 77.1% of other healthcare professionals used complementary therapies[18]. This situation shows that the worldwide use of TCM methods is increasing day by day. The most important thing is to ensure that these methods are used conscientiously by trained and certified practitioners.

In this study, the AHCAMS mean score was found to be 26.86±7.46, and the Holistic Health sub-dimension mean score was found to be 10.94±4.32. The results of our study were found to be similar to the literature in terms of showing that midwives and nurses have positive and moderately positive attitudes towards complementary and alternative medicine. In the study of Teke et al[19]., the mean AHCAMS score was 27.96 ± 5.49. In the study of Cırık et al[20]., it was stated that nurses consider TCM practices to be useful, effective, and cheap, and their attitudes were positive. The positive attitudes of healthcare professionals towards complementary therapies are an important factor in communicating with and supporting individuals in line with their needs.

When the knowledge of the midwives and nurses about TCM methods was examined, it was determined that 75.4% of them knew ozone therapy, 73.8% of them knew leech therapy and 73.4% of them knew cupping therapy. In the study of Özşaker[21], it was determined that senior nursing students had the most knowledge about music therapy (94.6%), acupuncture (93.3%), hypnosis (92.4%), and leech therapy (82.6%). In the study of Yayan and Dag[22], it was determined that 49.1% of the nurses had knowledge about herbal treatments, 36.6% had knowledge about acupuncture, 37.5% had knowledge about music therapy, and 33.9% had knowledge about massage and meditation, and that the nurses involved did not know many TCM practices. In another study, a majority of healthcare professionals (50-75%) reported that they had sufficient knowledge about herbal, spiritual, alternative, and physical types of CAM, but not about energy therapy and therapeutic methods[18]. These results suggest that experimental studies on these methods are useful in understanding the current state of knowledge of these methods. These methods, that used especially by midwives and nurses, have less side effects than modern medicine for support or treatment, safe and It is preferred because it is a non-risky method.

In the study of Cristina et al[23]., patients emphasized that it was important to ask about previous experiences regarding the use of TCM. In the current study, the rate of use of TCM by the patients of midwives and nurses was 69%. This rate was found to be 59.4% in the study of Kocabaş et al[24]., 73.7% in the study of Lotfi et al[25]., and 84.7% in the study of Onyiapat et al[26]. These results show that caregiver midwives and nurses should update their knowledge about TCM methods, and they will be better able to inform individuals about TCM by participating in training programs involving methods they do not yet know.

According to our study findings, there is a significant relationship between age, occupation, and having a chronic disease, and the mean scores of the scale. According to our study, nurses' attitudes towards complementary therapies were found to be better. It is thought that the reason for this is that nurses' attitudes are better because they encounter people with different chronic diseases more. In many studies in the literature,[27,28]., a statistically significant difference was found for the use of CAM practices between the students according to gender, and department. It is similar to our study. Differently from our study findings, in study of Demir[19] on healthcare professionals, it is stated that there is no statistically significant relationship between the mean scores of scale and socio-demographic variables such as gender, marital status, presence of chronic disease,

educational status, and occupation. While Demir's[19] work was done in a big city, our work was done in a rural area. In the literature, it is stated that the use of CAM applications is more especially in rural areas[29]. The level of use of complementary therapies by people living in rural areas is high. It is thought that the difference in the findings may be due to this.

CONCLUSION

As a result, although the midwives and nurses lacked knowledge about Traditional and Complementary Medicine methods, their attitudes were found positive and they were willing to receive training. The use of complementary and alternative treatments allows midwives and nurses to provide holistic care and enables society to turn to the right practices in this process and keeps them away from harmful practices. For this reason, all midwives and nurses interested in/or practicing TCM should be encouraged to gain necessary skills in this field by participating in training programs. Evidence-based TCM treatment should be included in midwifery and nursing education programs. Midwives and nurses should not only know the strengths and limitations of TCM methods but should also be able to inform all segments of society about the effectiveness and possible risks of these procedures. It is clear that more research is needed to evaluate the awareness of these methods, when to apply them, their prevalence, safety, efficacy, and economic benefits.

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ORIGINAL RESEARCH

Effect of Salat Activity on Knee Pain, Range of Motion and Muscle Strength after Total Knee Arthroplasty: A Single-Blinded Randomized Controlled Trial

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Abstract

Objectives: The aim of this study was to investigate the effect of salat activity on knee pain, muscle strength and range of motion after posterior stabilized total knee arthroplasty.

Material-Method: This prospective randomized study was conducted in KTO Karatay University and Medova Hospital, Konya, Türkiye, between March 2019 and June 2019. Thirty volunteers between the ages of 55 and 75 who had undergone total knee arthroplasty participated in this study. Participants were randomly divided into two groups as Physical therapy group and Physical therapy + salat group. The participants in the physical therapy group were provided hot-cold application, transcutenous electrical nerve stimulation (TENS), active-assisted range of motion, stretching and strengthening exercises during four weeks. Physical therapy+salat group performed salat activity in addition to the treatment. The knee joint patency was measured using a digital goniometer, muscle strength using a manual muscle tester, knee pain with the visual analogue scale (VAS).

Results: There was no difference in knee flexion and extension muscle strength between the groups before and after treatment ($p > 0.05$). There was no difference in VAS values between the groups before and after treatment ($p > 0.05$). Knee flexion angle increased significantly in the physical therapy+prayer group compared to the post-treatment physical therapy group ($p<0.003$). There was no significant difference between the groups in knee extension angle before and after treatment ($p>0.05$).

Conclusion: In this study, it was found that Salat activity after knee arthroplasty improved knee joint range of motion.

Keywords: Arthroplasty, Exercise, Knee, Randomized Controlled Trial, Salat

INTRODUCTION

Islam is one of the major religions in the world. The number of its believers worldwide is expected to increase by 35% between 2010 and 2030 that would reach up to 2.2 billion.[1] Salat activity is a form of worship that is compulsorily performed five times a day by the people who practice Islam. During the salat activity, the person performs different body movements while reading the Arabic prayer.[2] The salat activity begins when a person turns their face to the Qibla and takes their hands to their ears and then join them at the navel or chest (standing or Qiyam). After standing for 60-90 seconds, the hands are placed on the knees, and the person tilts their body forward (bowing or ruku). The action of tilting forward takes approximately 5-10 seconds before returning to the standing position. Subsequently, the prostrate (sujud) movement is made. In the prostrate position, the forehead, knees and hands are in contact with the ground. The prostrate position lasts 5-10 seconds on average. Then the person moves from prostrate to sitting position (tahiyat). Full flexion of the knees occurs in the sitting position. The sitting and prostrate positions are repeated twice. The sum of these movements is called rakat. There are a total of 40 rakats in fivetimes of Salat activity per day.[3,4] Brown and Lee [5] defined exercise as planned and repetitive movements of the body. Exercise helps in the maintenance of physical fitness and has many beneficial effects on health. Salat activity is a kind of exercise because it includes planned and repetitive body movements. In the literature, there are studies that indicate the physical and mental positive effects of salat activity on human health.[6]

Total knee arthroplasty is one of the most common skeletal-muscle surgeries worldwide.[7] The most common post-operative problems are pain in the knee, joint restriction and decreased muscle strength. In the first months after the surgery, power loss of the quadriceps muscle can be around 60%.[8,9] In the early post-operative period, the most important factor that affects the patient`s ability to walk is the range of motion. To gain normal range of motion as soon as possible is important in rehabilitation.[10] For these reasons, taking the patient into the rehabilitation programme as early as possible reduces the time of recovery, hospitalisation time and cost.[11] The post-operative rehabilitation programme includes elevation, cryotherapy, continuous passive motion (CPM), neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), bandaging, water therapy, strengthening and stretching exercises.[12] In particular, post-operative stretching and strengthening exercises are important in restoring joint range of motion and muscle strength.[13,14] Salat is an activity that involves large muscle groups and joints in the lower extremities.[4] Nevertheless, there are no studies that examined the effects of salat activity after total knee arthroplasty in the literature. The aim of this study was to investigate the effects of salat activity on pain, range of motion and muscle strength after posterior stabilized total knee arthroplasty.

MATERIALS AND METHODS

Ethical considerations

A prospective randomized controlled trial was conducted. The study protocol was approved by the KTO Karatay University`s Non-Clinical Research Ethics Committee dated 25/09/2018 and with the decision of 2018/004. The research was conducted in accordance with the principles of the Declaration of Helsinki. Before the conduct of the study, detailed information was given about the procedures to be performed and each participant signed the informed consent.

Patients

A total of 30 volunteers with sedentary lifestyle aged between 55- and 75 years participated from the Orthopedic Services of the Medova hospital in Türkiye, from March 2019 to June 2019. All patients had primary osteoarthritis. The patients who could not achieve adequate recovery (patients with an average knee flexion of 90 degrees and a VAS assessment of more than 7 units) with the home exercise programme were also included in the study, whereas those with post-operative lower extremity infection, circulatory disorder, wound complications and instability were excluded. All patients were performing regular salat activities before surgery. This prospective randomized study was conducted in KTO Karatay University and Medova Hospital, Konya, Türkiye, between March 2019 and June 2019.

The participants were randomly divided into two groups, physical therapy group (PT-G) (n = 15) and physical therapy + salat (PT + S-G) group (n = 15). The participants in both groups were included in the study 30 days after the operation with the approval of the specialist that performed the surgery. The participants in the PT-G were provided hot-cold application (hot: 20 min, cold: 10 min) , TENS (treatment parameters were: alternating current, rectangular impulse, impulse duration 100 µs, frequency of 100 Hz, 20-min duration of a single treatment) , active-assisted range of motion (knee flexion-extansion) , stretching and strengthening exercises (contraction of isometric knee and hip muscles,lifting straight leg and hip abduction-adduction with tolerated weight, knee flexion and extansion, ankle flexion and extansion. All moves consisted of 3 sets of 10 repetitions) based on the oedema status by a physiotherapist five days a week for four weeks. Participants in the PT-G were also given a classic home exercise program for their application 5 times a day while PT+S-G was not given. In addition, the participants were told to salat activity on chair during the study period. The same PT protocol was applied to the participants in the PT + S-G, but the participants performed five salat activities each day for 4 weeks. Participants in the PT + S-G received support from their relatives for a certain period of time (average 7 days) in the prostration position. In this process, the physiotherapist informed the patient and their relatives on a daily basis and ensured the correct execution of the procedure. Patients in the PT + S-G their daily salat activities on video record during the study and sent the images they took daily to the specialist physiotherapist. In this way, it was provided to perform salat activities correctly. Before and after the study, knee flexion-extension muscle strength was measured with a manual muscle testing device (LaFayette Instrument Company, Lafayette, IN, USA), knee range of motion with digital goniometer and pain sensation in the knee with VAS.

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Randomisation and blinding

The study process is shown in figure 1. The study was designed as single-blind. The participants were randomly divided into groups with the help of a computer program. The researcher who made the measurements has no information about the groups. When the data entry was completed, the principal investigator added the group assignment to the data set. The statistician performed the statistical analysis without knowing the groups.

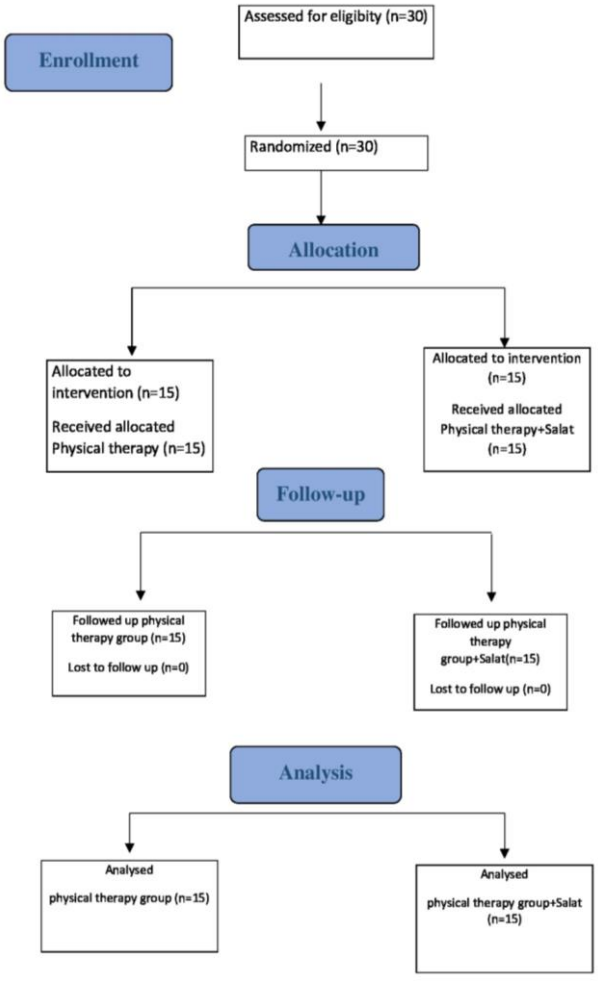

Figure 1. The patient selection process and study flow

Outcomes

The quadriceps and hamstring muscle strength was measured with LaFayette brand digital hand dynamometer. For quadriceps force measurement; The test was initiated with the participants sitting on a flat floor with their hips and knees flexed at 90 °, feet free and without support. The participants were verbally informed about the test application technique before starting the test. The dynamometer was placed perpendicular to the leg, 1-2 cm above the level of the malleoli. During the test, the "break test" technique, which requires isometric contraction, was applied.[15] For hamstring strength measurement, the participant was asked to lie prone on a flat table, with the knees flexed at 90° and without support. The muscle strength was measured using the same technique mentioned above. All measurements were taken twice by the same researcher from both legs of the participants in kg with the same hand and the best measurement was accepted. The patients' postoperative knee flexion ranges were measured with a digital goniometer (Halo digital goniometer, LaFayette). Goniometric measurements were taken with the patient in the prone position. The center of the goniometer was placed on the lateral epicondyle of the femur. Measurements were made so that the fixed arm passes through the midline of the femur and the movable arm passes through the midline of the fibula. Compensatory movements of the patient were not allowed. At the start of the study the digital goniometer was calibrated by measuring a 90° angle. The VAS is a simple scale that evaluates the severity of pain. It consists of a straight line of 10 cm. A value of 0 means no pain, a value of 10 means severe pain.[17]

Surgical procedure

Operation used a standard median parapatellar approach. All surgeries utilized the Scorpio PS posterior-stabilized system (Stryker, Mahwah, New Jersey).

Sample size and statistical analysis

Sample size calculation was made using a statistical power analysis program (G*Power Version 3.0.10, Franz Faul, Universität Kiel, Germany). It was calculated according to the previous study examining the effect of TENS and exercise on knee pain.[18] Pain level was used to estimate the sample size. The analysis indicated that fifteen participants for each group were enough to detect a large effect of Cohen's d:(0.75) with an alpha error probability of 0.05 and the power of 80%. SPSS for Windows 25.0 (IBM SPSS Statistics for Windows, Version 25.0., IBM Corp., Armonk, NY, USA) was used for the statistical analysis of the data. Normally distributed data were evaluated by Student`s *t* test, and non-parametric tests were used. Mann-Whitney U test was used for the intergroup analysis, and Wilcoxon signed rank test was used for comparison of first and last values in the intra-group analysis.

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The descriptive statistics were expressed as mean ± standard deviation. A *p* value less than 0.05 was considered statistically significant.

RESULTS

There were 13 women and 17 men as participants in this study. The mean age of the PT-G was 63.8±1.03, and that of the PT+S-G was 59.6±1.45. There was no statistically significant difference in knee angles, pain intensity and muscle strength between the two groups at the beginning of the study (pre-study group comparison: p=0.568 for knee flexion angle, p=0.836 for knee extension angle, p=0.243 for pain intensity, p=0.516 for knee flexion strength, p=0.789 for knee extension strength).

The muscle strength values of the participants before and after the treatment are given in Table 1. There was a statistically significant difference in knee flexion strength and knee extension strength post-treatment compared with pre-treatment in both groups ($^1p<0.001$). Nevertheless, there was no significant difference in the muscle strength between the PT+S-G and PT-G ($^2p>0.05$).

Pre- and post-treatment VAS values of the participants are given in Table 2. There was a statistically significant difference in VAS values post-treatment compared with pre-treatment in both groups ($^1p<0.001$). However, there was no significant difference in the VAS values between the PT+S-G and PT-G ($^2p>0.05$).

Table 1. Muscle strength values of the groups before and after treatment
*According to Wilcoxon signed rank test

Groups	**Physical therapy group**			**Physical therapy + Salat group**			
	Before treatment	After treatment	In group P^1	Before treatment	After treatment	In group P^1	Between groups p^2
Knee Flexion Strength (kg)	5.99 ± 0.71	7.61 ± 1.08	**< 0.001***	6.20 ± 1.48	7.53 ± 1.09	**<0.001***	0.771
Knee Extension Strenght (kg)	8.34 ± 1.01	10.2 ± 1.06	**< 0.002***	8.30 ± 1.07	10.03 ± 0.79	**<0.001***	0.724

Table 2. VAS values of the groups before and after treatment

Groups	**Physical therapy group**			**Physical therapy + Salat group**			
	Before treatment	After treatment	In group P^1	Before treatment	After treatment	In group P^1	Between groups p^2
VAS (cm)	7.92 ± 1.57	2. 35 ± 0.87	**< 0.001***	8.73 ± 1.09	2.40 ± 1.45	**< 0.001***	0.219

*According to Wilcoxon signed rank test

The knee joint patency values of the participants before and after treatment are given in Table 3. There was a statistically significant difference in knee joint patency values in both groups after the treatment ($^1p<0.001$).

The knee flexion angle increased significantly in the PT+S-G compared with the PT-G ($^1p<0.003$). Nevertheless, there was no significant difference between the PT+S-G and PT-G regarding knee extension ($^2p>0.05$).

Table 3. Knee joint patency values of the groups before and after treatment

Groups	**Physical therapy group**			**Physical therapy + Salat group**			
	Before treatment	After treatment	In group P^1	Before treatment	After treatment	In group P^1	Between groups p^2
Knee flexion angle (°)	90.46 ± 8.70	124.93± 3.63	**< 0.003***	91.44 ± 10.29	140.06 ± 1.81	**< 0.001***	**< 0.003****
Knee extension angle (°)	13.6 ± 3.88	4.80±1.85	**< 0.001***	12.40 ± 5.60	4.46 ± 2.66	**< 0.001***	0.802

*According to Wilcoxon signed rank test
**According to Mann-Whitney U test

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DISCUSSION

This study showed that salat activity had a positive effect on knee joint range of motion in the participants with total knee arthroplasty but it did not affect knee pain and muscle strength.

The incidence of knee osteoarthritis (OA) and rheumatoid arthritis (RA) has been steadily increasing in the last decade. As a result, severe knee pain, muscle weakness and gait disturbances are seen.[19] Total knee arthroplasty (TKA) is considered to be an appropriate and effective method for the treatment of knee OA and RA. The main purpose of the TKA procedure is to reduce knee pain and improve knee function. Great attention should be paid to post-operative knee mobility or range of motion (ROM) to accommodate daily living activities.[20] After the TKA procedure, approximately 1.3% of the patients have severe joint restriction.[21] Rowe et al.[22] stated that the knee flexion angle should be more than 120° to reduce the risk of fall after surgery and to perform daily activities in the most appropriate way Similarly, in our study, knee flexion angle was more than 120° after the treatment in the PT + S-G. Classical TKA can relieve the patient's pain, but the flexion range is usually around 100° -110° .[23] In recent years, the search for more flexion after TKA has continued. Passive-active knee flexion-extension exercises and CPM device are the most commonly used methods for post-operative knee ROM.[24] Nevertheless, rehabilitation exercises may cause pain, and severe pain may delay healing.[25] Exercises with the use of the CPM device cause less pain, but the CPM device is difficult to carry and is expensive [21]. In the salat activity sitting position (tahiyat), the knees are in full flexion (approximately 130°-150°) for an average of 30-60 seconds.[26] The patient performs a controlled knee flexion five times a day during the salat activity. Also, during the salat activity, the person moves independently so that he or she can perform the knee flexion appropriately by setting the pain limit during the knee flexion. Muslim patients with knee osteoarthritis have been shown to have a significantly better flexion range than non-Muslim patients with knee osteoarthritis.[27] In addition, it is known that worshiping has a positive spiritual effect. Many studies show that salat in the postoperative recovery period positively affects patients.[28,29] Our findings reveal that salat activity improves knee flexion angle.

In this study, no statistically significant difference in the muscle strength and VAS values was observed between the groups. This may be because the salat activity is described as a moderate exercise. To date, there is no study on energy expenditure during the salat activity. Nevertheless, it is stated that performing similar activities, such as yoga and tai chi result in about 4 calories per kilogram per hour spent (for example, in a 70 kg individual; 70 × 4 = 280 cal / hour).[30] In a recent review, the effects of weightless forward bending, squatting exercises and salat activity on lower extremity muscles were examined. It was found that there was no significant difference between the activities of voluntary maximal contraction of rectus femoris, biceps femoris and gastrocnemius muscles.[26] Safee et al.[31] examined the electromyography (EMG) levels of the rectus femoris, biceps femoris and gastroknemius muscles during salat activity or squatting exercise, consequently, they found no significant difference among the activities. In another study, the myoelectric activity of the gastrocnemius muscle during salat activity or plantar flexion of the ankle was examined and no significant difference was found between the activities.[32] Similarly, although there was a statistically significant difference in the muscle strength in both groups, there was no significant difference between the groups.

There are many studies that indicate standard physiotherapy exercises (e.g. strengthening, stretching or aerobic exercise) in post-operative rehabilitation reduce knee pain and stiffness and improve quality of life.[32,33] In this study, the VAS values decreased significantly in both groups but there was no statistically significant difference between the groups. This may be due to the fact that salat activity increases parasympathetic activity and suppresses sympathetic activity. The sympathetic system is activated in stress situations that cause pain. Stimulation of the sympathetic system causes the release of endogenous opoioids from the prefrontal region, anterior cingulate gyrus, insula, amygdala and hypothalamus in the brain. Suppression of the sympathetic system may cause pain to increase and prolong.[34] In a recent review, it was reported that parasympathetic activation is high and sympathetic activation is low in religious people, and they also have low cortisol levels.[35] Doufesh et al. [3] studied the effect of salat activity on the autonomic nervous system in a study conducted with 30 Muslim men. As a result of the

study, the researchers found that salat activity increased the parasympathetic activity and suppressed the sympathetic activity The results of this study revealed that pain sensation decreased in both groups, but this decrease was caused by the PT. The present study had some limitations. First of all, we designed a 4-week program and presented the short-term effects. Secondly, we did not have a long-term follow-up. Further studies needed for the observation of long-term gains after the intervention.

CONCLUSION

In conclusion, in this study, it was observed that salat activity improved knee joint ROM in patients with TKA but it had no effect on pain and muscle strength. In the literature, studies on the biomechanical aspect and health effects of salat activity are limited. Therefore, future comprehensive studies on the biomechanics of salat activity and their health effects are needed.

Source of finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

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Author contributions: All authors contributed equally while this study preparing.

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ORIGINAL RESEARCH

The Examination of the Use of Traditional, Complementary and Alternative Medicine and Practices by Turkish Citizens and Syrians under Temporary Protection

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Abstract
Objective: As of the mid-twentieth century, rapid advances in disease diagnosis and treatment had increased the use of complementary and alternative therapies.
Material-Method: This study was conducted among Syrians under temporary protection aged 18 and over and Turkish citizens in the province of Elazig, located in the Eastern Anatolia region of Türkiye. In order to compare Syrian and Turkish citizens, each group was calculated as 295 people.
Results: Participants learned about Traditional Complementary and Alternative Medicine and Applications most frequently from family. The first three methods mostly used by Syrians under temporary protection were the use of herbal products with 93.9%, bloodletting therapy and cupping therapy with 46.8%. Among Turkish citizens, the first three mostly used methods were the use of herbal products with 88.1%, cupping therapy with 13.6%, and bloodletting therapy with 10.5%. While 98.0% of Turkish individuals reported experiencing side effects from traditional complementary medicine practices, 46.1% of Syrians under temporary protection reported experiencing side effects.
Conclusion: Participants learned about Traditional Complementary and Alternative Medicine and Practices most frequently from family members. Access to information on this subject should be facilitated. Awareness-raising studies should be carried out, especially in the use of herbal products.
Keywords: Complementary Medicine, Syrians, Alternative Therapies

INTRODUCTION

Human beings have been using Traditional Complementary and Alternative Medicine and Practices since the beginning of their existence. However, there has been an increase in the use of complementary medicine practices since the middle of the twentieth century, in line with the rapid developments observed in diagnosis, nursing, and treatment [1]. Furthermore, the increase in chronic, degenerative, and malignant diseases that are difficult to nurse and treat as life expectancy increases, as well as the high cost of new technologies, the difficulties in accessing these opportunities, the inability of healthcare team members to spare enough time, the suspicion of current nursing and treatment methods and fear of possible side effects have also greatly increased the interest in complementary medicine practices [2].

Alternative medicine is defined as any health service that is used instead of medical treatment and is not accepted by modern biomedicine or treatments. On the other hand, complementary medicine is a treatment and healthcare system that is used in addition to medical treatment [3]. Terms related to complementary and alternative medicine are typically grouped under a single heading. Complementary and alternative medicine is defined

as a system of diagnosis, treatment, and protection, which is formed by diversifying the conceptual framework of medicine, or by meeting the demands that cannot be met traditionally and adding integrity to fundamental medicine [4].

Interest in traditional and complementary medicine practices continues. The use of traditional medicine methods is widespread worldwide [5].Traditional medicine is the sum of knowledge, abilities, and practices used for health protection such as the prevention of physical and mental illnesses, their diagnosis, recovery, and treatment, that are based on theories, beliefs, and experiences specific to different cultures that can or cannot be explained. The terms "complementary medicine" and "alternative medicine" are used interchangeably with traditional medicine. These correspond to a wide range of health practices that are not part of that country's traditional practices and are not integrated into the existing health system [6]. In a study conducted by Patricia et al. in the USA, it was determined that 62% of the participants used any of the complementary and alternative treatments [7]. According to studies conducted around the world and in our country, the usage rate of Traditional Complementary and Alternative Medicine and Practices is 42.1% in the US, 48.2% in Australia, 49.3% in France, 70.4% in Canada while in developing countries, the rates are 40% in Colombia, 71% in Chile, 70% in China and 80% in African countries [8]. This rate has been determined to be 65.8% in Türkiye [9].

The aim of the present study is to determine the use of Traditional Complementary and Alternative Medicine and Practices by Syrians under temporary protection and Turkish citizens living in the region.

MATERIALS AND METHODS

This descriptive and cross-sectional study was conducted among Syrians under temporary protection aged 18 and over and Turkish citizens in the province of Elazig, located in the Eastern Anatolia region of Türkiye. According to 2020 records, 12202 Syrians live under temporary protection in the region constituting the population of the study. The n= Nt 2 2nd 2 pq/d 3 2nd 3 (N-1)+t 4 2nd 4 pq formula is used to determine the sample group. The frequency of the usage of alternative and complementary medicine was determined to be 80% in the sample calculation following the pilot study conducted among 20 Syrian participants under temporary protection. The number of people to be sampled was calculated as 295 with a 97% confidence interval and 5% deviation. The study included the same number of Turkish citizens as the control group. The total number of samples was determined as 590 people. The study was conducted in the Healthy Living Center and Migrant Health Center between 01.02.2021 and 01.03.2021. The inclusion criteria of the study are being a Syrian under temporary protection over the age of 18 and being a Turkish citizen.

Following the necessary literature review, the questionnaires were created. Questionnaires were administered by the researchers who would carry out the study by making face-to-face interviews. Participation in the questionnaire was based on voluntariness, and the questionnaires were administered only after participants had been informed and signed a consent form.

The obtained data were saved in the package program, and error checks, tables, and statistical analyses were performed through this software. The means are presented with standard deviations. As statistical analysis methods, the X^2, t-test, and variance analysis were used.

Ethical statement

Necessary permissions were obtained from the Directorate General of Migration Management, dated 25.04.2018 and numbered 91541139-000/97. The necessary permission was obtained from Fırat University Non-Interventional Research Ethics Committee, dated 14.01.2021 and numbered 2021/01-29.

RESULTS

The average age of the participants included in the study was 40.05±15.93. The average age of Syrians under temporary protection was 37.11±15.30, while the average age of Turkish citizens was 43.02±16.03. While 59.2% of Syrians under temporary protection were male, 54.1% of Turkish citizens were female. While 32.2% of Syrians under temporary protection are high school graduates, 50.7% have extended families, 34.9% of Turkish citizens are university graduates and 86.7% have nuclear families (Table 1). The average household number among Syrians under temporary protection was 7.48±2.16 people, while it was 3.92±1.53 among Turkish citizens (Table 1).While 37.3% of Turkish citizens had a chronic illness and 94.9% consulted a doctor due to health problems, 26.4% of Syrians under temporary protection had a chronic illness and 99.3% consulted a doctor when they experienced health problems.

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Table 1. Socio-demographic characteristics of participants.

	Syrian		Turkish Citizen		Statistical analysis	
	N	%	N	%		
Age	37.11±15.30		43.02±16.03		t:4.505	P<0.001
Gender						
Male	174	59.0	136	46.1	X^2:9.815	P:0.002
Female	121	41.0	159	53.9		
Educational status						
Illiterate	54	18.3	40	13.6		
Primary school graduate	51	17.3	58	19.7		
Secondary school graduate	66	22.4	37	12.5	X^2:61.685	P<0.001
Highschool graduate	95	32.2	57	19.3		
University graduate	29	9.8	103	34.9		
Smoking						
Yes	95	32.2	80	27.1		
No	182	61.7	188	63.7	X^2:3.183	P:0.204
Stopped	18	6.1	27	9.2		
Average age of starting smoking	18.85±4.01		18.01±2.38		F:8.489	P:0.123
Family structure						
Nuclear family	145	49.2	256	86.8	X^2:95.916	P<0.001
Extended family	150	50.8	39	13.2		
Average household member	7.48±2.16		3.92±1.53		t:17.241	P<0.001

According to our research, when faced with any health problem, 6.4% of Turkish participants use non-prescription drugs, and 38.6% apply to Traditional Complementary and Alternative Medicine and Practices. Among the Syrians, these rates are 3.1% and 32.5%, respectively. Almost every participant (99.3%) had heard of traditional and complementary medicine. The most used information sources were family members, radio and television broadcasts, and the internet. The benefit rate among participants was 95.1%. The rate of those who experienced side effects was 75%. (Table 2).

The first three traditional and complementary medicine methods most used by Syrians under temporary protection were the use of herbal products (93.9%), the use of bloodletting (46.8%), and cupping therapy (46.8%). Among Turkish citizens, the first three methods that are commonly used were the use of herbal products (88.1%), cupping therapy (13.6%), and bloodletting therapy (10.5%). Traditional Complementary and Alternative Medicine and Practices were most used to strengthen the immune system in both groups. The rate of those who stated that Traditional Complementary and Alternative Medicine and Practices were beneficial was 95.1% (Table 3).

DISCUSSION

Family members, radio-television broadcasts, and the Internet were the most common sources of information for the Traditional Complementary and Alternative Medicine and Practices of participants. The rate of those who received information from healthcare professionals was relatively low. The rate of getting information from healthcare professionals for Traditional Complementary and Alternative Medicine and Practices was found to be significantly higher than that of Syrians under temporary protection. The study conducted by Tan et al. supports our findings [10]. According to a study conducted in Türkiye, 13% of people consult a doctor about Traditional Complementary and Alternative Medicine and Practices [11]. Consequently, the principle that the expected benefit of a drug outweighs the potential risk applies to both traditional products and synthetic pharmacological agents [12]. Several studies have reported that Traditional Complementary and Alternative Medicine and Practices may cause side effects [12,13]. Therefore, it is important to carry out studies to ensure that people have access to reliable information sources about Traditional Complementary and Alternative Medicine and Practices.

In our study, both groups had a high rate of consulting a doctor for health problems. It was determined that when Syrians under temporary protection experience health problems, they visit a doctor at a significantly higher rate than Turkish citizens (p<0.05). No significant difference was

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found between the rates of using non-prescription drugs and resorting to Traditional Complementary and Alternative Medicine and Practices in either group when faced with health problems (p>0.05) (Table 2). There are studies supporting our finding [14].

Table 2. Information resources about traditional complementary and alternative medicine and practices.

	Syria		*Türkiye*		*Statistical analysis*	
	N	**%**	**N**	**%**		
Have you ever heard of traditional medicine methods?	295	100	291	99.7	X^2:4.027	P:0.045
Where did you hear it from?						
Family	299	99.3	266	90.2	X^2:24.820	P<0.001
Radio-Television	220	74.6	211	71.5	X^2:0.697	P:0.404
Internet	108	36.6	98	33.2	X^2:0.746	P:0.388
Books	19	6.4	17	5.8	X^2:0.118	P:0.731
Newspaper	0	0.0	10	3.4	X^2:10.172	P:0.001
Conference/Seminar	0	0.0	4	1.4	X^2:4.027	P:0.045
Healthcare professionals	0	0.0	21	7.1	X^2:21.775	P<0.001
Regarding traditional treatment methods;						
Received training	3	1.0	2	0.7	X^2:0.185	P:0.667
Benefited from	273	97.8	268	92.4	X^2:8.980	P:0.030
Experienced side effects	136	46.1	289	98.0	X^2:196.953	P<0.001

The rate of those who stated that they benefited from Traditional Complementary and Alternative Medicine and Practices among the participants was found to be more than 90%. The rate of Syrians under temporary protection who stated that they benefited from Traditional Complementary and Alternative Medicine and Practices was found to be significantly higher than Turkish participants (p<0.05).

Several studies support our findings [11,15–17]. The most used traditional complementary medicine practices among the participants were determined to be herbal medicine use (91.0%), the use of cupping therapy (30.2%), and the use of bloodletting (28.6%). The use of these three methods was found to be significantly higher among Syrians under temporary protection than among Turkish participants (p<0.05), (Table 3).

Table 3. The Traditional Complementary and Alternative Medicine and Practices the participants use.

Method	**Syria**		**Türkiye**		**Statistical analysis**	
	N	**%**	**N**	**%**		
Herbal medicine	277	93.9	260	88.1	X^2:5.991	p: 0.014
Acupuncture	0	0.0	13	4.4	X^2:13.293	P<0.001
Music/Painting/Dance	0	0.0	12	4.1	X^2:12.249	P<0.001
Homeopathy	5	1.7	5	1.7	X^2:0,000	p: 1.000
Chiropractic	85	28.8	14	4.7	X^2:61.186	P<0.001
Osteopathy	78	26.4	3	1.0	X^2:80.496	P<0.001
Ozone application	3	1.0	9	3.1	X^2:3.062	p: 0.080
Cupping	138	46.8	40	13.6	X^2:77.266	P<0.001
Hirudotherapy	16	4.4	20	6.8	X^2:0.473	p: 0.491
Bloodletting	138	46.8	31	10.5	X^2:94.940	P<0.001
Larval therapy	3	1.0	2	0.7	X^2:0.202	p: 1.000
Mesotherapy	0	0.0	2	0.7	X^2:2.007	p: 0.157
Prolotherapy	5	1.7	0	0.0	Fischer X^2:5.043	p: 0.061
Hypnosis	0	0.0	3	1.0	X^2:3015	p: 0.082
Zone therapy	0	0.0	0	0.0		

Prolotherapy (95.1%), mesotherapy (92.4%), and homeopathy (91.4%) were found to be the least known methods among the participants (p<0.5), (Table 5). A study conducted in Malaysia discovered differences in the use of Traditional Complementary and Alternative Medicine and Practices among different parts of the country. This result supports our study. It is an anticipated result

that having different cultures will affect the use of complementary medicine practices [18]. According to the WHO report, the number of countries with herbal medicine regulation between 1999 and 2019 has nearly doubled, reaching 124 countries [19]. According to the same report, one of the methods that are among the most used Traditional Complementary and Alternative Medicine and Practices worldwide is the use of herbal medicine. Studies are stating that herbal medicine use is common [19,20].

In our study, it was discovered that Traditional Complementary and Alternative Medicine and Practices were used to strengthen the immune system (79.8%), with the belief that it will work (59.5%), in addition to doctor treatment and to treat digestive system disorders (47.3%). When the intended purpose of Traditional Complementary and Alternative Medicine and Practices was compared between the two groups, it was discovered that Turkish citizens used it significantly more for hair and face care, weight loss, and addiction treatment ($p<0.05$). It was discovered that the rate of using Traditional Complementary and Alternative Medicine and Practices for infertility, the likelihood that it will work, musculoskeletal diseases, dermatological diseases, digestive system disorders, neurological diseases, respiratory system diseases, and immune system strengthening were significantly higher among Syrians under temporary protection($p<0.05$). (Table 3).

In the study of Oral et al [9], it is most commonly used due to a chronic disease and pain problem. In our study, when some characteristics of the participants regarding the traditional and alternative medicine usage purposes were examined, the most common usage purposes were Strengthening immune system, Does no harm, May be helpful and In addition to medical treatment. however, it was determined that the least usage purposes were Paralysis, chronic neurological diseases and Anxiety and Depression/Psychological issue. (Table 4). This difference may be due to the different sample groups.

Table 4. Some characteristics of the participants about traditional and alternative medicine usage purposes.

The reasons to use traditional and alternative medicine	*Syria*		*Türkiye*		*Statistical analysis*	
	N	**%**	**N**	**%**		
General state disorder	77	26.1	58	19.7	X^2:3.467	p: 0.063
Reducing stress	11	3.7	16	5.1	X^2:0.644	p: 0.422
Losing weight and addiction	6	2.0	19	6.4	X^2: 7.059	p:0.008
Facial care and haircare	31	10.5	50	16.9	X^2: 5.166	p:0.023
Sound sleep/Lack of sleep	31	10.5	27	9.2	X^2: 0.306	p:0.580
Stopping the advancement of the illness	49	16.6	20	6.8	X^2: 13.803	P<0.001
Strengthening immune system	273	92.5	198	67.1	X^2: 59.212	P<0.001
Digestive system disorder	210	71.2	69	23.4	X^2: 135.184	P<0.001
Respiratory system diseases	90	30.5	8	2.7	X^2: 82.279	P<0.001
chronic neurological diseases	10	3.4	2	0.7	X^2: 5.444	p:0.020
Anxiety and Depression/Psychological issue	7	2.4	9	3.1	X^2: 0.257	p:0.612
Backache, low back pain and shoulder ache	153	51.9	58	19.7	X^2: 66.585	P<0.001
Migraine, headache	23	7.8	22	7.5	X^2: 0.024	p:0.877
Muscle pain, muscle spasm	93	31.5	28	9.5	X^2: 43.926	P<0.001
Dermatological diseases	56	19.0	36	12.2	X^2: 5.151	p:0.023
Joint, tendon and ligament diseases	42	14.2	10	3.4	X^2: 21.596	P<0.001
Paralysis	6	2.0	3	1.0	X^2: 1.015	p:0.314
In addition to medical treatment	112	38.0	201	68.1	X^2: 53.902	p<0.001
Infertility	11	3.7	26	8.8	X^2: 6.488	p:0.011
Does no harm, may be helpful	217	73.6	134	45.4	X^2: 48.451	p<0.001
Desperation	30	10.2	34	11.5	X^2: 0.280	p:0.596

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In the researches, it is seen that the participants mostly know the bloodletting and cupping therapy. However, in the researches, it was determined that the participants knew the least mesotherapy, prolotherapy and homeopathy therapy [21,22]. In this study, it was seen that the participants were mostly known for bloodletting cupping and herbal medicine therapy, however, mesotherapy, prolotherapy and homeopathy was the least known. (Table 5).

Table 5. Participants' knowledge levels about traditional and alternative treatment methods.

Information	Never heard of it		Just heard of it		Know it generally		Know it well	
	N	%	N	%	N	%	N	%
Herbal medicine	6	1	31	5.3	380	64.4	173	29.3
Apitherapy	318	53.9	247	41.9	24	4.1	1	0.2
Hypnosis	256	43.4	217	36.8	115	19.5	2	0.3
Acupuncture	249	42.2	213	36.1	124	21.0	4	0.7
Hirudotherapy	80	13.6	352	59.7	139	23.6	19	3.2
Homeopathy	539	91.4	31	5.3	19	3.3	1	0.2
Chiropractic	298	50.5	46	7.8	222	37.6	24	4.1
Cupping	81	13.7	96	16.3	189	32.0	224	38.0
Bloodletting	59	10.0	126	21.4	173	29.3	232	39.3
Maggot debridement therapy	503	85.3	69	11.7	15	2.5	3	0.5
Art therapy	399	67.6	165	28.0	24	4.1	2	0.3
Mesotherapy	545	92.4	33	5.6	12	2.0	0	0.0
Prolotherapy	561	95.1	15	2.5	13	2.2	1	0.2
Osteopathy	309	52.4	51	8.6	212	35.9	18	3.1
Ozone application	413	70.0	142	24.1	32	5.4	3	0.5
Zone therapy	430	72.9	143	24.2	15	2.5	2	0.3

CONCLUSION

It has been concluded that Traditional Complementary and Alternative Medicine and Practices are widely used among both Syrians under temporary protection and Turkish citizens. The vast majority of those who use Traditional Complementary and Alternative Medicine and Practices intend to use them in addition to strengthening the immune system as an addition to medical treatment. Most participants stated that these methods were beneficial to them. Herbal medicine is the most used traditional treatment method. Especially herbal remedies can cause side effects. Most participants learned about complementary and alternative medicine from their families, television and radio broadcasts, and the internet. The rate of those who received training on Traditional Complementary and Alternative Medicine and Practices is less than 1%. It was discovered that the participants' use of books or seminars as a source of information was quite low. Clearly, studies should be conducted to ensure the reliability of information sources. The Ministry of Health should play its part in terms of conducting a more effective education program on the proper use of traditional and complementary medicine remedies.

Limitation

Since Syrian and Turkish citizens were not matched, this may have caused a limitation in statistical comparisons.

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Author contributions: Conceptualization: [FK]; Design: [FK]; Writing: [FK, YO, FB]; Investigation/Data collection: [CP, BA, AK, RG, FK, FB]

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ORIGINAL RESEARCH

Determination and Comparison of Phenolic Compound Content and Antimicrobial Activity of Some Propolis Samples in Türkiye

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Abstract
Objective: Ethanol extraction is the most popular technique for the production of propolis extracts. However, this method may not be suitable for various clinical conditions. Based on it, we composed a trial product with an olive-oil extraction as an alternative method. Furthermore, we crafted combinations to reinforce and synergize the antimicrobial activity of the trial propolis product. Finally, we compared our trial products with the existing marketing products in Türkiye. The present study aimed to determine chemical compounds and the antimicrobial activity of some propolis samples selected from Türkiye and compare the mentioned features with the olive-oil- trial products we composed for the study.
Material-Method: Four different samples, as trial and final products, were crafted for the study. Trail products conducted as sample 1 to 4 (S1, S2, S3 and S4). The trial products were compared with the four other propolis and propolis-containing combined products currently exciting on the market. Four different trademarks were used, and the Trademarks (TM) was called TM1, TM2 TM3, and TM4. Determination of Total Phenolic Compound (TPC) was analyzed according to the Folin-Ciocalteau method. The antimicrobial activity test was determined according to the Kirby-Bauer method.
Results: The highest TPC ratio was detected in the trademark 2 (TM2), and the lowest TPC ratio was determined in the TM4 samples, 19553.12 GAE mg/L and 740.9 GAE mg/L, respectively. The TPC ratio of the final trial product sample 4 (S4) was defined as 6519.3 GAE mg/L. The highest inhibitation zone against *E. coli, K. pneumoniae, S. aureus* strains was observed in S1 (the oleuropein-containing trial product). The highest inhabitation zone against *C. albicans and C. krusei* yeasts was observed in TM1 and S4 (the oleuropein-and boron-containing trial propolis product) samples.
Conclusion: The S4 product, containing boron, oleuropein, and propolis, had a higher inhibitation zone diameters compared to the commercial brands. Furthermore, all the propolis products analyzed in this study had rich phenolic components; the curative and beneficial impacts of phenolic components on health merit further investigations.
Keywords: Propolis, Oleuropein, Boron, Antimicrobial Activity, Phenolic Compounds

INTRODUCTION

Natural living and well-being are a brand trend throughout the world. The steadily rising antibiotic resistance and the increasing healthcare costs may substantially impact.[1]Utilization of a supplementary prepared to treat infectious diseases is widespread as complementary or alternative medicine; propolis is one of the agents commonly preferred beside or alternative to drugs.

Propolis is a natural resinous mixture that has been empirically used for centuries, expecting an immunomodulatory effect.[2]

Propolis is a honeybee (Apis mellifera) product with a broad spectrum of benefits, such as antibacterial, antiviral, antifungal, antioxidant, immunomodulatory, and anti-inflammatory effects.[3] The most-reported biological activity of propolis extracts is its antimicrobial effect; it is widely used to prevent or treat various diseases.[4] The wide use of propolis for different purposes makes it a subject of academic interest.

Propolis is a substance that is difficult to standardize. The bioactive compounds and the chemical structure of propolis vary depending on the endemic vegetation of the region it has been obtained from.[5-7]

Subsequently, the pharmacological effect of propolis differs.[8] The phenolic contents of propolis extracts or a propolis-natural product combination product in the market are always different. The biological activity of extracted propolis is a result of phenolic components. The phenolic compounds play an essential role in human well-being;

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apparently, they have antimicrobial, anti-allergic, anti-inflammatory, and antioxidative effects.[9] The TPC of propolis also differs from the extraction technique and the solvent used.[10]

Because ethanol is the best-known solvent for propolis, ethanol extraction is the most common and effective method to extract propolis.[11] However, it has some disadvantages; it may be not favored in a particular group of the population, it has a strong residual adore, it may be not suitable for the treatment of some ophthalmological cases, pediatric patients, and patients with alcohol intolerance.[12-13] Therefore, in our study, we experimented with olive oil extraction as an alternative method to extract propolis. In addition, numerous studies have reported olive oil polyphenols' antioxidant and antimicrobial activity.[14]

We crafted combined trial propolis samples for the study; with some additional ingredients, we aimed to reinforce and synergize the antimicrobial activity of propolis. We compared the trial samples with market trademark analogs. This study aimed to determine and compare the chemical structure and bioactivity of the olive oil-extracted propolis samples with the existing trademark samples.

MATERIALS AND METHODS

Reagents and chemicals

Refined olive oil was used for the extraction. Other materials used in the product trials (oleic acid, polyethylene glycol 400 (PEG 400), Oleuropein, boron, methanol, Folin-Ciocalteau reagent, Na_2CO_3, gallic acid) were delivered from the Sigma-Aldrich® company.

Propolis extraction

Raw propolis was obtained from a local producer. Different attempts were made for the appropriate combination. To determine the proper dose and the raw material to be used, separate samples were prepared and evaluated in terms of efficacy and phenolic content. The samples prepared are given in Table 1. For propolis extraction, 100 g of raw propolis was frozen at -20 ○C for 24 hours, then passed through a blender and ground into powder.

The final extract was obtained by maceration with olive oil at 25 ○C for 24 hours.

Commercial propolis products

Four different commercial products were selected to compare the effectiveness and TPC of Olive oil-extracted propolis with commercial products in the market. The features of the trademark products are given in Table 2.

Table 1. Trial samples created for the propolis product

Sample	Contents
S1	Oleuropein, Peg 400, Water
S2	Olive oil-extracted propolis
S3	Olive oil-extracted propolis, Oleic acid
S4	Olive oil-extracted propolis, Oleuropein, Boron

Table 2. Commercial propolis products were used in the comparison.

Trademark	Contents
TM1	Water-based propolis extract
TM2	Water-based propolis extract
TM3	Zinc, Vitamin C, Herbal supplement, Water-based propolis extract
TM4	Zinc, Vitamin C, Ethanol based propolis extract

Total phenolic compound determination

The determination of TPC was analyzed according to the Folin-Ciocalteau method. All samples were studied in triplicate. The samples to be tested were diluted with methanol (1:4). 800 µl of 0.5 N Folin-Ciocalteau reagent was mixed with 40 µl of test samples and allowed to react for 5 minutes in the dark at room temperature. Afterward, 800 µl of Na2CO3 (10%) was added, and the volume of the mixture was increased to 3.0 ml with distilled water. The mixture was incubated at room temperature for 30 minutes. The absorbance was measured at 760 nm using a spectrophotometer. Gallic acid solution was used as a standard to construct the calibration curve. In the tested samples, TPC was expressed as mg/L gallic acid equivalent (GAE).

Antimicrobial activity

Antimicrobial activity was determined by the disc diffusion (Kirby-Bauer) method (15,16). The microorganism test medium prepared at McFarland 0.5 turbidity was inoculated on Mueller Hinton Agar (MHA, Merck). Test specimens were impregnated with a blank disc (Bioanalyase, blank disc, 6mm). The discs were placed on the agar plate and incubated for 24 hours at 37°C. Gentamicin (Bioanalyse, CN 10µg disc), streptomycin (Bioanalyse, S 10µg disc), and nystatin (Bioanalyase, NY 100U disc) were used as positive controls. Staphylococcus aureus ATCC 25923, Klebsiella pneumoniae ATCC 13883, Escherichia coli ATCC 25922, Candida albicans (Clinical isolate), C. krusei (Clinical isolate) strains were used for the analysis. All experiment performed in triplicate and data are given as mean (± SD).

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RESULTS

Total phenolic compound content

The highest TPC rate was determined in the TM2 sample; 19553.12 (GAE mg/L). The TPC rates obtained from the trial samples were as follow: S1 9446.98 (GAE mg/L), S2 10088.27 (GAE mg/L), S3 5373.03 (GAE mg/L), S4 6519.30 (GAE mg/L). Fig.1 demonstrates the TPC ratio of the study samples.

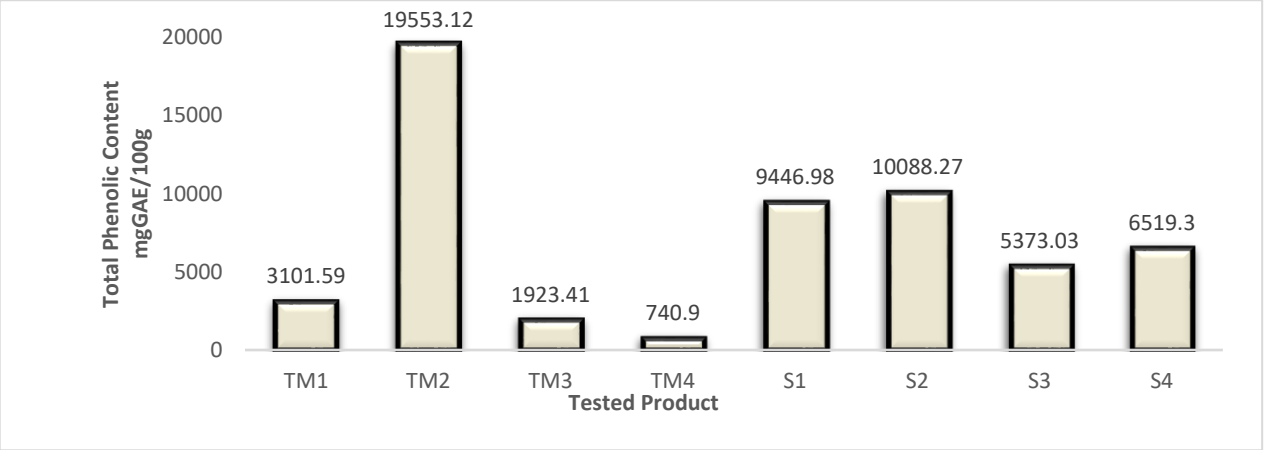

Figure 1. The Phenolic Compound Content of the study samples.

Antimicrobial effect of the products

It has been determined that TM1 has a high effect on Candida strains and no activity against bacteria. The S1 product, containing oleuropein, performed the highest antimicrobial effect against bacteria. TM3 was effective against gram-positive bacteria, and it did not show any activity on gram-negative bacteria. Bacterial strains were generally resistant to market products. TM1 and S4 showed the highest activity against yeasts. Table 3 represents the antimicrobial zone diameters of the products in detail.

Table 3. Zone Diameters of the Test Products

	Zone Diameter (mm) (±SD)				
Product	***E.coli***	***K. pneumoniae***	***S.aureus***	***C.albicans***	***C.krusei***
TM1	R	R	R	15 ±1.15	20 ±0.57
TM2	8 ±0.57	7 ±0.57	10 ±1	11 ±1.52	12 ±0.57
TM3	R	R	10 ±1.15	R	R
TM4	R	R	R	R	R
S1	15 ±2	17 ±0.57	20 ±0.57	R	R
S2	10 ±3	R	R	10 ±1.15	8 ±1.15
S3	11±0.57	10±0.57	11±1.73	R	R
S4	15 ±2.51	16 ±1.15	14 ±2.51	16 ±0.57	20 ±0.57
Gentamicin	25 ±0	22 ±1.15	25 ±0		
Streptomycin	20 ±0	20 ±0	20 ±0		
Nystatin				25 ±0	20 ±0

TM:Trademark, S: Sample, R:Resistant, ±SD:Standart deviation

DISCUSSION

Propolis is a product widely used in folk medicine from ancient times to the present day. Various pharmacological properties have been revealed and reported in the literature.

In their study, Markiewicz et al. have shown a significant reduction in the growth and proliferation of tumor cells with the propolis derivates.[17] Furthermore, in vivo studies represented a positive

effect of propolis on the dysbiosis of the gut microbiota; some studies suggest propolis as a potential agent in the treatment of intestinal diseases such as colitis.[18,19]

The antibacterial effect of propolis has been demonstrated against many gram-positive and gram-negative bacterial strains in vitro analyzes.[20] Propolis has antifungal activity against *Candida* and dermatophyte strains.[21] The antiviral activity against *Herpes simplex* and *Herpes zoster* viruses has been reported.[8,22,23] There are also reports from dentistry investigations; observational studies report successful results in treating dental inflammation, propolis positively contributes to the oral microbiota. A clinical study reports a positive efficacy of propolis-containing mouthwash in reducing plaque index and gingival index.[24]

The phenolic components are responsible for the antimicrobial activity of propolis. Studies show that propolis has more than 300 components. However, the content and variety of phenols vary depending on the solvent or the extraction method used.[25-27]

According to our study, the highest rate of TPC was detected in the TM2 sample (19553.12 GAE mg/L); its antimicrobial activity was not excessive, however. Probably, the reason is not the amount but the variety of phenolic compounds it contains because it is known that not every phenolic component has an antimicrobial property.

The components of a natural product determine the biological action spectrum. For example, phenolic compounds have many pharmacological impacts such as antioxidant, antiproliferative, antiviral, antifungal, antibacterial activities.[28,29]

The TPC ratio in TM3 (1923.41 GAE mg/L) was lower than other products; this may be related to the quantities of the compounds or the extraction method. The TM3 product had no antimicrobial effect against strains except for *S. aureus*, and the TM4 product had no antimicrobial effect against any tested microorganism. We consume that the antimicrobial ineffectiveness of the TM3 and TM4 products may be due to insufficient active substance concentration; because we know that the biological activities of phenolic compounds are dose-dependent.[29,30]

The TM1 and TM2 products had evident inhibition zone against *Candida* strains. The S1 sample had the highest zone diameter activity; the antifungal activity against yeasts. In their study, Kubiliene ve ark. (2015) have reported different antimicrobial activities, and the variation was considered to differ with the phenolic compound.

We prepared the final S4 product based on the S1, S2, S3 samples we crafted previously. As the highest inhibitation zone diameter was detected in the S4 sample, we claim that the boron and oleuropein together with propolis have a synergic antimicrobial effect. Boron is a semi-metal that has antimicrobial effects against many microorganisms. Boron is widely used in oral medical products as it prevents biofilm formation.[31-33] However, MIC (minimal inhibitation concentration) doses should be determined of the products and further studies should be conducted to determine the significance of these zones of inhibition.

CONCLUSION

The sample we developed (S4 product containing boron, oleuropein, and propolis) had higher inhibitation zone diameters against bacteria and yeasts compared to the commercial samples. The TPC ratio in the S4 sample was found twice higher than in TM1 and approximately six times higher than TM3 and TM4. TM2 product contains over three times more phenolic compounds compared to the S4 sample. Therefore, we may claim that olive oil-extracted propolis could be a better alternative method for ethanolic extract. Considering that all propolis extracts analyzed in the present study are rich in phenolic components, we suggest that they benefit well-being. Further researches should be carried to determine the phenolic compound diversity.

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ORIGINAL RESEARCH

Evaluation of Aqueous Stem Bark Extract of *Guiera senegalensis* on Wistar Rats

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Abstract

Objective: Global herbal products however have enormous potential as natural drugs and are of vast commercial significance, are often processed and procured without being scientifically evaluated for their toxicity. This study evaluated the toxicological effects of *Guiera senegalensis* on wistar rats.

Material-Method: An acute toxicity evaluation was carried out to determine the LD_{50} of *Guiera senegalensis* stem bark extract where eleven (11) rats were used. Sub-acute toxicity was carried out to determine the effect of the plant extract on some liver and kidney function parameters and haematological parameters. For sub-acute toxicity studies, twenty (20) rats were randomly placed into 4 groups of 5 rats each. Group 2, 3 and 4 were orally treated with aqueous stem bark extract of *Guiera senegalensis* at a daily dose of 200, 400 and 800 mg/kg body weight (b.wt.) respectively for 28 days while group 1 served as a control group.

Results: Alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase and bilirubin levels increased significantly as dose increased. No significant increase in K^+ and urea was observed in group 2 and 3 treated with 200 and 400 mg/kg respectively. However, significant increase was observed in group 4 treated with 800 mg/kg. Na^+ and Creatinine showed significant increase when compared with control group. Red blood cells, packed cell volume, and haemoglobin concentrations decreased significantly whereas a significant increase was observed in white blood cells with increase in dose respectively.

Conclusion: The aqueous stem bark extract of *Guiera senegalensis* have a dose-dependent toxic effect on liver, kidney and haematology of Wistar rats.

Keywords: Toxicological Evaluation, *Guiera senegalensis*, Liver, Kidney, Haematological Parameters

INTRODUCTION

Nearly all cultures use plants as a source of medicine from ancient times to present day, hence, a considerable percentage of people in both developing and developed countries use medicinal plants to remediate, alleviate or treat both human and animal diseases[1]. As a consequence, medicinal plants are now of substantial significance due to the special characteristics they possess as a large source of therapeutic phytochemicals, that may lead to the discovery and development of novel drugs as most of the phytochemicals from natural sources such as phenolics and flavonoids have been reported to have positive impact on health and disease prevention[2]. Ethnobotanical studies confirmed that indigenous plants are the main sources of traditional medicines[3-4]. Thus, there has been increase in herbal drugs usage globally with about 70% - 80% of the African population relying on nonconventional drugs which are predominantly of herbal sources both locally manufactured and imported[4-5]. However, most of these herbal drugs are often processed and procured without been scientifically evaluated for their safety.

The plant *Guiera senegalensis* a member of the family combretaceae is a tropical shrub widely distributed around the globe with high diversity in Africa and Asia growing on leached soils, fallows, and mostly on sandy soil and on very dry stations[6] to a height of 3 to 5 m depending on the habitat[7]. *G. senegalensis* has been used to treat various illness where the same plant part is used to treat a number of different diseases and at the same time different parts of the plant used to treat the same disease[7]. It has been used to relief aches and pains and for treating fever and malaria[8-9]. It has also been reported to possess healing properties against respiratory congestion and cough[10], to ease breathe and treat bronchial disorder, severe diarrhea and

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dysentery[9, 11]. It's safety has not been well documented. Hence this study evaluated the effects of aqueous stem bark extract of *G. senegalensis* on Wistar rats by determining the effects of the extract on haematological parameters, liver and kidney functions.

MATERIALS AND METHODS

Plant material

Fresh stems of *G. senegalensis* were collected from Song Local Government Area, Adamawa state. The plant material was taxonomically identified by a Botanist in Botany Department of Adamawa State University, Mubi, Nigeria where the voucher specimen was deposited.

Experimental animals

Thirty-one (31) mature and healthy Wistar rats (both sexes) weighing about 180 g to 200 g obtained from the Animal Resource Unit, National Veterinary Research Institute (NVRI) VOM, Plateau State, Nigeria were used for the study. The animals were housed at room temperature in wired cages for one week acclimatization before the initiation of the experiment where a 12 h light/dark cycle was maintained. An ethical clearance for conducting the experiment on research animals was secured from the University Ethical Committee prior to the initiation of the experiment with an approval number of IACEC/ANP-A045/2021

Extraction of plant material

G. senegalensis stem bark was washed, peeled and dried for four weeks under shade and was then pulverized to powder form using mortar and pestle. Maceration method of extraction described by Abdullahi and Mainul[12] was used to extract the powdered *G. senegalensis* stem bark. The powdered plant material was soaked in distilled water and allowed to stand at room temperature where it was stirred every 24 h for a period of three (3) days in order to soften and break the cell wall of the plant to release the soluble phytoconstituents. After three days, the mixture was pressed and strained by filtration, and the solvent was evaporated using a water bath and crucible at 40^0c until the extract was dried.

Phytochemical analysis

The qualitative phytochemical method described by Sofowara[13] and Banu and Catherine[14] was used to analyze the phytochemical constituents of aqueous *G. senegalensis* stem bark extract.

Acute toxicity

After one week of acclimatization according to criteria, the method described by Chinedu *et al.*[15] was used for acute toxicity determination. The method is categorized into 3 separate stages with the result of each stage determining whether to further proceed to the next stage or end the process. The result of the final test was validated using a confidence (confirmatory) test. Eleven rats were used in total. At stage 1 four rats were divided into 4 groups of 1 rat each and were treated with 50 mg/kg, 200 mg/kg b.wt., 400 mg/kg b.wt., and 800 mg/kg of *G. senegalensis* stem bark extract. The rats were closely observed for 1 h post-administration and 10 min every 2 h space interval for 24 h. The testing proceeded to stage 2 if mortality was not recorded. In stage 2, three rats were divided into 3 groups of 1 rat each and were treated with 1000 mg/kg b.wt., 1500 mg/kg b.wt., and 2000 mg/kg b.wt. of the stem bark extract of *G. senegalensis* which were closely observed for 1 h post-administration and 10 min every 2 h space interval for 24 h. The testing proceeded to stage 3 if no mortality was recorded. In stage 3, three rats were divided into 3 groups of 1 rat each and were treated with 3000 mg/kg b.wt., 4000 mg/kg b.wt., and 5000 mg/kg b.wt. of *G. senegalensis* stem bark extract which were also observed closely for 1 h post-administration and 10 min every 2 h space interval for 24 h. Finally, 1 rat was used for the confirmatory stage and was treated with 5000 mg/kg b.wt. of the *G. senegalensis* stem bark extract and was observed closely for 1 h post-administration and 10 min every 2 hours space interval for 24 h.

Table 1. Doses for acute toxicity determination of aqueous *G. senegalensis* stem bark extract

Stages	Group 1	Group 2	Group 3	Group 4
1	50 mg/kg	200 mg/kg	400 mg/kg	800 mg/kg
2	1000 mg/kg	1500 mg/kg	2000 mg/kg	
3	3000 mg/kg	4000 mg/kg	5000 mg/kg	

Sub-acute toxicity

Three (3) doses were administered to rats for 28 days for sub-acute toxicity determination. The doses administered for sub-acute toxicity study were chosen based on the result acquired from the acute toxicity study. Twenty (20) rats were grouped into 4 groups of 5 rats each. The rats were grouped accordingly: group 1 received normal saline only, group 2 received 200 mg/kg b.wt. extract, group 3 received 400 mg/kg b.wt. extract and group 4 received 800 mg/kg b.wt. extract.

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Sample collection

After 28 days of daily administration, the rats were weighed and sacrificed by decapitation 24 h after the last dose was administered. The blood samples were collected and analyzed for haematological parameters based on the method described by Dacie and Lewis[16], liver function parameters (ALT and AST) based on the method described by Rietman and frankel[17], ALP based on the method described by Wright *et al.*[18], while bilirubin based on the method described by Penhaker *et al.*[19] and kidney function based on the method described by Rifai[20]. Cypress diagnostic kits were used for the analysis.

Statistical analysis

All data collected from the study were statistically recorded as mean ± standard error of mean. Statistical differences between the mean values were determined using Analysis of Variance Test (ANOVA). Duncan's Multiple Range Test was used for comparison. IBM SPSS statistics software version 27 was used to analyze all data collected.

RESULTS

Phytochemical analysis

Phytochemical components of aqueous *G. senegalensis* stem bark extract are presented in Table 2. Phytochemicals tested included alkaloids, flavonoids, saponins, tannins, steroids and terpenoids. The result disclosed the presence of all the phytochemicals tested for.

Table 2. Phytochemical constituent of aqueous *G. senegalensis* stem bark extract.

Phytochemical	Inference
Alkaloid	+
Flavonoid	+
Saponin	+
Tannins	+
Steroid	+
Terpenoid	+

Key: + = present

Acute toxicity

Oral administration of aqueous *G. senegalensis* stem bark extract did not produce mortality up to a dose level of 5000 mg/kg b.wt. The bodyweight, food and water consumption of the rats did not show any significant difference when compared with the control group. Signs of toxicity such as aggression, depression, writhing, diarrhea and hypermotility were not recorded in rats used for oral LD_{50} determination when compared with control.

Sub-acute toxicity

Table 3 shows the serum liver function parameters alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and bilirubin of rats treated with aqueous stem bark extract of *G. senegalensis* for 28 days. The result showed that the levels of liver parameters significantly ($p<0.05$) increased with an increase in dose of the extract when compared with the control.

Table 3. Effect of aqueous stem bark extract of *G. senegalensis* on liver function.

Parameters Groups	Alanine aminotranferase (IU/L)	Aspartate aminotransferase (IU/L)	Alkaline phosphatase (IU/L)	Total bilirubin (mmol/L)	Conjugated bilirubin (mmol/L)
1. Control	25.66 ± 1.20^{a}	94.33 ± 0.88^{a}	37.33 ± 0.33^{a}	7.63 ± 0.15^{a}	2.03 ± 0.03^{a}
2. 200 mg/kg b.wt	35.00 ± 0.58^{b}	103.33 ± 0.33^{b}	51.00 ± 1.00^{b}	8.63 ± 0.15^{b}	2.60 ± 0.12^{b}
3. 400 mg/kg b.wt	39.00 ± 0.88^{c}	121.66 ± 1.20^{c}	76.00 ± 1.16^{c}	12.33 ± 0.26^{c}	4.000 ± 0.58^{c}
4. 800 mg/kg b.wt	41.00 ± 1.15^{c}	141.33 ± 0.88^{d}	80.33 ± 1.45^{d}	13.50 ± 0.15^{d}	5.97 ± 0.09^{d}

All values are presented as mean ± SEM. Different superscripts down the column indicates that they are significantly different at ($p<0.05$), n=5

Values for AST, ALP and bilirubin of all the groups vary significantly with each other.Table 4 shows the serum kidney function parameters (urea, creatinine, Na^+ and K^+) of rats treated with aqueous *G. senegalensis* stem bark extract. Values of Na^+ and creatinine showed a significant ($p<0.05$) increase when compared with the control group whereas K^+ and urea values for group 2 and 3 did not differ significantly ($p<0.05$) when compared with the control group. However, group 4 that received 800 mg/kg b.wt. showed a significant increase when compared with the control.

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Table 4. Effect of aqueous stem bark extract of *G. senegalensis* on kidney function

Parameters Groups	Na^+ (mmol/L)	K^+ (mmol/L)	Creatinine (mmol/L)	Urea (mmol/L)
1. Control	137.67 ± 0.33^{a}	4.17 ± 0.07^{a}	25.00 ± 0.58^{a}	7.20 ± 0.12^{a}
2. 200 mg/kg b.wt	148.33 ± 0.67^{ab}	4.40 ± 0.06^{a}	36.33 ± 0.33^{b}	7.43 ± 0.09^{a}
3. 400 mg/kg b.wt	148.67 ± 0.33^{ab}	4.20 ± 0.12^{a}	45.66 ± 0.20^{c}	7.60 ± 0.12^{a}
4. 800 mg/kg b.wt	149.33 ± 0.33^{b}	5.07 ± 0.03^{b}	54.00 ± 1.16^{d}	8.67 ± 0.15^{b}

All values are presented as mean ± SEM. Different superscripts down the column indicates that they are significantly different at ($p<0.05$), n=5

Table 5 shows the haematological parameters, packed cell volume (PCV), haemoglobin (Hb), red blood cells (RBC) and white blood cells (WBC) of rats treated with aqueous *G. senegalensis* stem bark extract. PCV, Hb and RBC significantly decreased with an increase in dose of the extract while WBC significantly increased with an increase in dose when compared with control.

Table 5. Effect of aqueous stem bark extract of *G. senegalensis* on haematological indices

Parameters Groups	Packed cell volume (%)	Haemoglobin (g/dL)	White blood cells ($\times 10^9$/L)	Red blood cells ($\times 10^2$/L)
1. Control	36.00 ± 1.15^{c}	12.43 ± 0.80^{c}	9.80 ± 1.17^{a}	6.37 ± 0.26^{c}
2. 200 mg/kg b.wt	32.66 ± 2.03^{ab}	11.43 ± 0.38^{bc}	12.93 ± 0.49^{b}	5.87 ± 0.26^{b}
3. 400 mg/kg b.wt	32.33 ± 1.20^{ab}	10.53 ± 0.30^{ab}	13.77 ± 0.19^{bc}	4.90 ± 0.46^{ab}
4. 800 mg/kg b.wt	30.33 ± 0.33^{a}	9.57 ± 0.37^{a}	14.47 ± 0.32^{c}	4.12 ± 0.28^{a}

All values are presented as mean ± SEM. Different superscripts down the column indicates that they are significantly different at ($p<0.05$), n=5

DISCUSSION

Acute toxicity

The determination of LD_{50} is usually the first step in evaluating and screening novel drugs. It is an initial assessment and evaluation of toxic characteristics and manifestation of test substance[21]. Oral LD_{50} of aqueous stem bark extract of *G. senegalensis* was indeterminable up to a dose level of 5000 mg/ kg, thus the LD_{50} is greater than 5000 mg/kg. This may indicate that the aqueous *G. senegalensis* stem bark extract of is safe via the oral route. This is similar to the report of Moo *et al*.[22] in which no mortality was recorded up to a dose level of 5000 mg/kg of N-hexane extract of *Leptadenia hastata*.

Effect of aqueous stem bark extract of *G. senegalensis* on liver function

Liver is an important organ that performs different varieties of biochemical activities such as synthetic and excretory functions. Therefore, no single biochemical test is capable of identifying or detecting the general function of the liver[23]. The serum ALT and AST reflect the hepatocellular injury, serum ALP reflects the impaired bile excretion and bile flow, while the serum total and conjugated bilirubin represent the metabolic functions of the liver[24].

The observed significant increase in the liver function indices of the rats treated with aqueous *G. senegalensis* stem bark extract may indicate that the aqueous stem bark extract of *G. senegalensis* is dose dependently toxic to the liver. The increased levels of ALT may indicate damage to hepatocytes that results to the release of the enzymes into the circulation, increased ALP may indicate the effect of the stem bark extract that leads to both

intrahepatic and extrahepatic obstruction of bile flow and the increased bilirubin level may indicate haemolysis and overproduction of bilirubin induced by the stem bark extract of *G. senegalensis*. This result is consistent with the report of Ashafa[25] in which the aqueous leaves extract of *Felicia muricata* Thunb. affected the liver function parameters of Wistar rats.

Effect of aqueous stem bark extract of *G. senegalensis* on kidney

Serum creatinine concentration has been used for assessment and evaluation of kidney function which begins to rise only when the glomerular filtration rate (GFR) has by one-half diminished and thereafter the rise of creatinine is exponential to decline in GFR[26]. Urea, the by-product of protein and amino acid breakdown produced by the liver which is distributed throughout the intracellular and extracellular fluid is filtered out from the blood by the glomeruli in the kidney and is partially being reabsorbed with water. It is another frequent biochemical parameter for estimating kidney function which is useful in the differential diagnosis of acute and pre-renal conditions[27]. Electrolytes are negatively and positively charged ions that are found within extracellular fluids and cells, blood and plasma. Test for serum electrolytes such as measurement of sodium, and potassium is used to evaluate renal functions and comprehensive metabolic biochemistry profiles.

The increased Na^+ may indicate that the aqueous *G. senegalensis* stem bark extract causes alteration in osmotic pressure that leads to dehydration and a consequent increase in Na^+. The increased K^+ may indicate the poor function of the kidney thus may lead to abnormal or sometimes fatal cardiac arrhythmias[28]. The increase in the K^+ level may indicate that the membrane channels were affected by the stem bark extract or the plant stem bark may have a hyperkalemic effect. Hyperkalemia occurs most often in renal failures leading to declined potassium excretion[29-30]. The increased serum creatinine and urea concentration may indicate that there is decreased GFR by the kidney due to the effect of the aqueous *G. senegalensis* stem bark extract. This result is not in agreement with the reports of Unuofin[31] in which the whole-plant aqueous extract of *Vernonia mespilifolia* Less. did not affect the biochemical parameters of Wistar rats.

Effect of aqueous stem bark extract of *G. senegalensis* on haematological parameters

Haematological parameters are valuable in observing and monitoring the toxicity of substances. RBCs are involved in the transport and distribution of oxygen in the body and transports CO_2 to the lungs; WBCs functions to defend the body by phagocytosis against foreign invaders, fight infections and to produce, transport and distribute antibodies throughout the body during immune response[32].

The decrease in PCV and Red blood cells count may indicate that the stem bark extract of the plant may have haemolytic effect as reflected by the increased total bilirubin. This may lead to hyperkalemia and consequently disturbances in acid-base balance when administered at higher doses. The decrease in the level of haemoglobin may indicate anaemia as a result of erythrocyte haemolysis caused by the aqueous *G. senegalensis* stem bark extract which may lead to decreased oxygen transport to tissues as well as transport of CO_2 back to the lungs. The increased WBC may indicate that the plant may have some toxic compounds which trigger the immune response leading to the production of more immune cells. This study supports the report of Ilham *et al*.[33] in which the leaves of *Ambrosia maritima* affected the haematological parameters of Nubian goats.

This study is limited to four functional parameters of liver and kidney and haematological parameters.

CONCLUSION

In conclusion, considering the serum level of biochemical parameters and the haematological parameters of the experimental rats treated with different oral doses of aqueous *Guiera senegalensis* stem bark extract, it suggests that the stem bark extract of the plant may be toxic especially at higher doses and longtime exposure.

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REVIEW

Effect of Body Acupuncture on Pregnancy-Related Low Back Pain and Pelvic Pain: A Systematic Review

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Abstract
Objective: The aim of the authors of this study was to determine the effect of body acupuncture on the symptoms of low back pain and pelvic pain suffered during pregnancy.
Material-Method: In this systematic review, 8 international databases (Cinahl, PubMed, Web of Science, Google Scholar, Science Direct, Scopus, Ebsco Host, Cochrane Library) comprising the period between January 2000 and March 2020 were screened. Articles that are not in English and Turkish were excluded. Three authors screened the related articles based on the titles and abstracts independently of each other.
A data extraction form was filled in for each appropriate study. The quality of the studies included in the study was assessed using the Jadad scale and PRISMA guidelines.
Results: Finally, six studies conducted in 3 countries between January 2000 and March 2020 with 838 pregnant women with complaints of low back pain and pelvic pain were included in the review. The results showed that body acupuncture reduced pregnancy-related low back pain and pelvic pain complaints and that it had no side effects.
Conclusion: We think that body acupuncture, a non-pharmacological method, will help clinicians to relieve the symptoms of pregnancy-related pelvic pain and low back pain.
Keywords: Body Acupuncture, Pregnancy, Low Back Pain, Pelvic Pain

INTRODUCTION

While pregnancy-related lower back pain (LBP) spreads from the upper part of the sacrum to the 12th costa, pelvic girdle pain (PGP) is felt near the sacroiliac joint, extending from the posterior iliac crest to the gluteal region.[1] The etiology of these pains that can last more than a week during pregnancy and may sometimes cause serious clinical problems is not exactly known.[2-4] The review of the literature demonstrates that approximately 34% to 76% of pregnant women experience lower back pain, pelvic girdle pain, or both.[5-10]

Lower back pain and pelvic girdle pain that are likely to affect activities of daily living and quality of life during pregnancy are thought to develop due to hormonal, mechanical, circulatory and psychosocial changes.[11] In several studies conducted on the issue, many factors such as age, parity, physical activity, body mass index, exhausting working conditions, history of back pain and pelvic girdle pain and history of trauma to the pelvis have been reported to pose a risk for pregnancy-related pelvic girdle pain and lower back pain.[1,5,12-14] Pregnancy-related lower back pain and pelvic girdle pain usually begin in the 18th week of pregnancy and peak between the 24th and 36th weeks of pregnancy. The differential diagnoses of LBP and PGP are mostly similar, but taking a careful clinical history and physical examination may help make a definitive diagnosis.[1] In order to distinguish these two pains from each other, several pain provocation tests and palpation tests should be performed.[1,15] The treatment includes individualized education and training programs, physical therapy, exercise and medication use. In the trainings, the aim is to teach anatomy, ergonomics, correct posture, pain management strategies and relaxation techniques.[13,15] Physical

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therapy and exercise include practices that help gain muscle strength, flexibility and endurance, repair injured tissues and maintain normal activities of daily living.[15,16] Today, in addition to these methods, many alternative and complementary therapies such as transcutaneous electrical nerve stimulation (TENS), acupuncture, massage and aromatherapy are used.[13,15,17] Acupuncture is among the Complementary and Alternative Medicine (CAM) methods that are frequently preferred in management of LBP and PGP.[21,22,24,28,29] Acupuncture is one of the oldest known therapeutic treatment forms that is characterized by inserting needles into a certain part of the body to stimulate a response.[18,43] Acupuncture is performed by inserting thin needles in acupuncture points in certain parts of the body for 15-20 minutes.[20] With the acupuncture method, all types of touch-sensitive and mechanically sensitive pain fibers and deep tissue receptors are activated.[44] Acupuncture, which is an effective method in treatment of chronic pain involves pain management mechanisms such as 'gate-control' spinal cord mechanisms, 'diffuse noxious inhibitory control (DNIC)' and top-down effects such as expectations of pain relief.[19,45-48] Acupuncture stimulation involves sensory-discriminative and affective dimensions. In the discriminative aspect, de qi, which is related to needling, includes a blend of various sensations, such as heaviness, numbness, soreness and distension. In the sensory aspect, acupuncture may rise feelings of calm and wellbeing in the person by activating C tactile fibers with mild manual tactile stimulation.[19] As a result of this, with the increased activity of C tactile afferents, 'limbic' touch response, which leads to the emergence of emotional and hormonal reactions, forms.[49] In the field of neuroscience, while it is thought that behavioral and neurophysiological response to C tactile afferents is well-established, the role of emotional touch in acupuncture stimulation is not well-known.[49] In the literature, it is stated that acupuncture provides effective analgesia in women suffering pregnancy-related PGP and/or LBP during pregnancy.[3-4,21-24,28,29] It is a realistic and urgent need to investigate the effectiveness and safety of the body acupuncture method used to reduce the symptoms of pregnancy-related pelvic girdle pain and lower back pain.

Aim and question of the research

In this systematic review, it was aimed to investigate and summarize the available evidence about the effectiveness of the body acupuncture method used to reduce the symptoms of pregnancy-related lower back pain and pelvic pain. The study sought answers to the following question: What is the effectiveness of the body acupuncture method used to reduce pregnancy-related low back pain and pelvic pain symptoms?

MATERIALS AND METHODS

Design

In this quantitative systematic review, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used for the analysis of previously published articles.[25] The PRISMA checklist ensures a clear and transparent review of the articles included in review for the integrity of the review. In this study, the focus was on the search of articles analyzing the effectiveness of the body acupuncture method used to reduce pregnancy-related lower back pain and pelvic girdle pain.

After duplicate articles were eliminated, the study was carried out through a three-stage process:

1. Screening of the relevant articles based on their titles and abstracts,
2. Article selection based on the reading of the entire text,
3. Analysis of the texts by at least two of the four referees independently of each other (ASK, SDA, ND, SKO). One of the referees analyzing the texts was not included this study.

Search methods

This study was carried out by retrospectively screening papers published between January 2000 and February 2020 to analyze the effectiveness of the body acupuncture method implemented to reduce pregnancy-related lower back pain and pelvic girdle pain. To this end, the CINAHL, Medline (Pubmed), Google Scholar, Science Direct, Isi Web of Science, Ebsco Host, Cochrane Library and Scopus databases were screened over the internet access networks of Kocaeli University and Kırklareli University by using the following search terms: "back pain", "lower back pain", "pelvic gridle pain", "pelvic pain", pregnancy", "pregnant women" and "acupuncture".

Search outcomes

Original studies which met the following inclusion criteria were included in the study:

1. Randomized controlled clinical trial studies (RCT)
2. Studies published in English or Turkish

3. Studies published between January 2000 and February 2020.
4. Studies conducted on the body acupuncture method, one of the acupuncture methods, used for reduction of pregnancy-related lower back pain and pelvic girdle pain.

After 500 duplicate articles were removed, three authors of the study (AS, ND and SDA) reviewed the remaining 97 articles. They determined whether or not the titles and abstracts of the articles met the inclusion criteria. In case of disagreement, the referees made a decision after discussing the matter. If the referees could not reach a consensus, then the fourth referee, who was not included in the study, was consulted. If the information in an article was considered insufficient, more information was requested from the author of the article via e-mail. The referees agreed that 97 articles were acceptable. After the full texts of these articles were read, some articles were excluded from the study due to the following reasons:

1. Studies in which the acupuncture application was not limited to the pregnancy period (i.e. the application started when the women had pain during pregnancy and continued in the postpartum period).
2. RCTs in which the ear acupuncture and Korean hand acupuncture methods were used.

Quality appraisal

The quality assessment of the studies was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions.[26] Therefore, the quality of the studies that were reviewed was rated using different methods to evaluate different designs of study.

Assessment of the risk of bias is part of the conduct and reporting of systematic studies. Within this context, the JADAD scale was used to assess the risk of bias and the quality of RCTs.[27] The JADAD scale consists of 3 items: describing randomization, blinding and accountability (dropout and withdrawals).

Rating process of randomization

If randomization was mentioned in the study, it was given 1 point, and if it was appropriate for the randomization method, it was given 1 point. Additionally, if it was inappropriate for the randomization method, 1 point was subtracted.

Rating process of blinding

If blinding was mentioned in the study, it was given 1 point, and if it was appropriate for the blinding method, it was given another 1 point. If it was not suitable for the blinding method, 1 point was subtracted.

Finally, we assigned 1 point if the accountability was known; if there were no data, the reason should have been stated. Scores to be obtained from the JADAD Scale range between 0 and 5. If the JADAD score is ≥3 points, the study is considered a high-quality study, and if it is ≤2 points, the study is considered a low-quality study.[27]

Similarly, the Consolidated Standards of Reporting Trials (CONSORT) checklist was used to assess the reporting quality of the studies. Studies that did not meet at least 70% of the items included in the CONSORT statements were considered to contain significant methodological flaws.

Data extraction

A data extraction document was prepared for the analyzed studies. In the document, the following information was recorded: the title, authors and publication year of the study, the country where the study was performed, type of the study, location of the study, inclusion criteria for the study, age and gestational age of the participants, sample size, data collection, details of the interventions and results.

RESULTS

Study selection

From the databases, 30,160 studies were selected. However, 29,660 of them were excluded because they were not in English or Turkish, or they were duplicates. As a result, 500 studies were screened based on their titles and abstracts. Of the 500 studies, 97 were reviewed in detail to assess their suitability. Finally, 6 studies were included. The process was summarized in a flow diagram in Figure 1. Detailed information of these 6 studies is given in Table 1.

Study characteristics

At the final stage, the authors agreed on 6 RCTs conducted between January 2000 and February 2020 to investigate the effect of body acupuncture method on women with pregnancy-related lower back pain and pelvic girdle pain. The sample sizes of the studies varied between 47 and 321 participants. The pregnant women in these studies were in the age group of 18-30 years. The quality of these 6 RCTs was assessed using the JADAD scale. The quality score range of these studies was ≥3. All of these 6 studies were included in the study based on the items studied.

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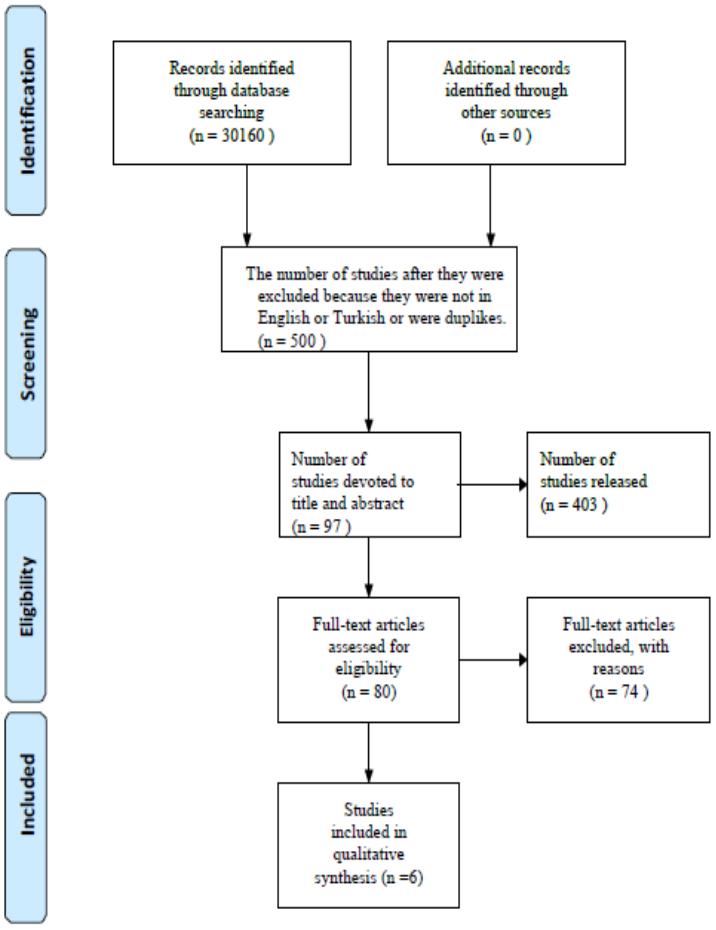

Figure 1. Study selection process

Interventions characteristics

Types of body acupuncture interventions and administration method

In the 6 studies reviewed in this study, the body acupuncture method was used. One of these studies was a prospective randomized open study conducted by Kvorning et al. in 2004.[4] The sample of their study conducted in Sweden included 72 30-year-old pregnant women whose gestational age ranged between 24 and 37 weeks. The Visual Analog Scale (VAS) was used to assess the severity of lower back pain and pelvic girdle pain in these women. Body acupuncture was applied on the pregnant women once or twice a week until they gave birth, or their pain was alleviated. At the end of the study, acupuncture was found to be effective in reducing pregnancy-related LBP or pelvic pain. The study was rated using the JADAD scale and given 3 out of 5 points.

In Elden et al.'s randomized controlled single-blind study conducted with 321 pregnant women whose gestational ages ranged between 12 and 31 weeks in Sweden (2005), the mean age of the participating women was 30 years.[21] The women suffered from pelvic girdle pain. VAS was used to assess the severity of their pain. The women participating in the acupuncture group underwent needle acupuncture application for 30 minutes twice a week for 6 weeks. The women participating in the other intervention group had six hours of stabilizing exercises for 6 weeks (exercise movements integrated into activities of daily living and increasing the mobility, strength and endurance capacity of the muscles were performed in short sessions several times throughout the day). The women participating in the control group received the standard treatment (education, home program for exercises and pelvic belt).

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Table 1. Effect of body acupuncture on pregnancy-related low back pain and pelvic pain

Effect of body acupuncture on pregnancy-related low back pain and pelvic pain: a systematic review and meta-analysis of randomized trials published between 2000 and 2020														
Type of Acupuncture	**Title of the manuscript**	**First Author Year**	**Country**	**Type of study**	**Place**	**Gestational age (weeks)**	**Age**	**Type of pain**	**Acupuncture sites**	**Sample size**	**Tools of data**	**İntervention (Treatment) arm**	**Comparison (Control) arm**	**Primary outcome**	**Quality**
Body-acupuncture	Acupuncture relieves pelvic and low-back pain in late pregnancy	Kvorning et al., 2004	Sweden	Prospective, randomized, open study	Maternity ward center	24-37 w	Average age 30 y	LBP or pelvic pain	LR3, GV20, local tender points	72	Visual analog scale (VAS)	Applied to the acupuncture points once or twice a week until the women gave birth or their pain was alleviated.	No additional treatment or no sham stimulation	The severity of pain in women in the acupuncture group was reported to be less than was that in the women in the control group. (60% acupuncture group vs 14% control group, P <.01).	Jadad: 3/5
Body-acupuncture	Effects of acupuncture and stabilizing exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomized single blind controlled trial	Elden et al., 2005	Sweden	Randomized single blind controlled trial.	Maternity care center	12-31 w	Average age 30 y	Pelvic gridle pain	GV 20, LI 4, BL26, BL32, BL33, BL 54, KI 11, BL 60, EX 21, GB 30, SP12, ST 36	321	Visiual analog scale (VAS)	1st group: Acupuncture was applied twice a week for 6 weeks. The duration of the application was 30 minutes (during this time, every 10 minutes, the needles were manually moved). Before and after the procedure, fetal heart rate and maternal heart rate, and maternal blood pressure were measured. 2nd group: Stabilizing exercises for 6 weeks.	Standard treatment consisting of advice, education, home program for exercises (increase strength abdominal and gluteal muscles), pelvic belt	Acupuncture stabilizing exercises are very effective in reducing pelvic girdle pain. It also effectively complemented the standard treatment.	Jadad: 4/5

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Table 1 (continue). Effect of body acupuncture on pregnancy-related low back pain and pelvic pain

Effect of body acupuncture on pregnancy-related low back pain and pelvic pain: a systematic review and meta-analysis of randomized trials published between 2000 and 2020															
Type of Acupuncture	**Title of the manuscript**	**First Author Year**	**Country**	**Type of study**	**Place**	**Gestational age (weeks)**	**Age**	**Type of pain**	**Acupuncture sites**	**Sample size**	**Tools of data**	**İntervention (Treatment) arm**	**Comparison (Control) arm**	**Primary outcome**	**Quality**
Body-acupuncture	Decrease of pregnant women's pelvic pain after acupuncture: A randomized controlled single-blind study	Lund et al., 2006	Sweden	Prospective randomized controlled single-blind study	Maternity health care center	22-36 w	Average age 29 y	LBP or pelvic pain	BL 27, 28, 29, 31, 32, 54, KI 11, CV 3, SP 6, LR 2, LI 4	47	-Nottingham Health Profile (NHP) questionnaire for health-related quality of life -Visual analog scale (VAS)	30-minute acupuncture was applied to the pregnant women who had pain twice a week for 5 weeks together with a physiotherapist.	Unclear	Acupuncture can be a suitable treatment for relieving pregnancy-related pelvic pain.	JADAD:3/5
Body-acupuncture	Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: randomized double-blinded controlled trial comparing acupuncture with non-penetrating sham acupuncture	Elden et al., 2008	Sweden	Randomized double-blinded controlled trial	Hospital, Antenatal care units	12-29 w	Average age 30 y	Pelvic girdle pain (PGP)	BL 26, 28, 32, 33, 54, 60, GV20, LI4, GB 30, EX 21, KI 11, ST36	107	Questionnaire (demographic data) -Visual analog scale (VAS) - European Quality of Life 5 Dimensions Questionnaire (EQ-5D) - European Quality of Life health instrument (EQ-5D VAS) - Oswestry Disability Index (ODI)	- Standard treatment (training on exercise to be done at home to strengthen the muscles in the abdominal and gluteal region was given) + acupuncture (12 30-minute acupuncture treatments, twice a week for 4 weeks and once a week for 4 weeks)	Standard treatment + non-penetrating sham acupuncture (the protocol applied to the experimental group was applied)	Acupuncture was found to have no significant effect on pain and degree of disease compared to penetrating sham acupuncture.	JADAD:5/5

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Table 1 (continue). Effect of body acupuncture on pregnancy-related low back pain and pelvic pain

Effect of body acupuncture on pregnancy-related low back pain and pelvic pain: a systematic review and meta-analysis of randomized trials published between 2000 and 2020															
Type of Acupuncture	**Title of the manuscript**	**First Author Year**	**Country**	**Type of study**	**Place**	**Gestational age (weeks)**	**Age**	**Type of pain**	**Acupuncture sites**	**Sample size**	**Tools of data**	**İntervention (Treatment) arm**	**Comparison (Control) arm**	**Primary outcome**	**Quality**
Body acupuncture	Evaluating acupuncture and standard care for pregnant women with back pain: the EASE Back pilot randomized controlled trial	Bishop et al., 2016	UK	Randomized single-blinding controlled trial	Antenatal and physiotherapy clinics, Hospital	13-31 w	18 years and over	LBP and pelvic girdle pain (PGP)	BL 23, BL 24, BL 25, BL 26, BL 27, BL 28, BL 54, BL 31, BL 32, BL 33 GB 30, HJJ L4, HJJ L5, GB 34, ST 36, LR 3, LI 4, BL 60, BL 62	91	Questionnaire - Oswestry Disability Index -Pelvic Girdle Questionnaire (PGQ) -EuroQol EQ-5D-5L -SF-12 - Numerical rating scale (NRS)	-1st group standard care (exercise approaches, heat, massage, manual therapy and issuing of pelvic supports/belts)+ true acupuncture: (6 to 8 20-30-minute treatment sessions were applied for 6 weeks) 2nd group standard care (exercise approaches, heat, massage, manual therapy and issuing of pelvic supports/belts)+ non-penetrating acupuncture (without needles, 0-30-minute hand acupuncture sessions were applied for 6 weeks)	-3rd group standard care: 2-4 treatment sessions for 6 weeks (exercise approaches, heat, massage, manual therapy and issuing of pelvic supports/belts)	No side effects of acupuncture were reported; however, long-term studies will help to understand the effect of acupuncture on pregnancy-related LBP and pelvic girdle pain (PGP) more clearly.	Jadad: 3/5
Body acupuncture	Cost-effectiveness of acupuncture versus standard care for pelvic and low back pain in pregnancy: A randomized controlled trial	Nicolian et al., 2019	France	Randomized control study	Hospital	16-34 w	18 years and over	Pelvic and low back Pain	40V, Weizhong and A Shi points	199	- Numerical rating scale (NRS) - Oswestry disability self-questionnaire—OSW -Visual Analog Scale (VAS)	-Standard care (pregnancy belt, lifestyle recommendations, and exercises, pain killer if necessary)+ acupuncture (needles were kept in the treatment area for 30 minutes during each session. 5 sessions were performed (2 of them in the first week. 3 of them in the next 3 weeks once a week)	-Standard care (pregnancy belt, lifestyle recommendations, and exercises, pain killer if necessary)	Acupuncture is an effective method to relive pregnancy-related pelvic and low back pain.	Jadad: 4/5

The results of the interventions demonstrated that acupuncture was superior to stabilizing exercises, and it supported the standard treatment significantly. The study was rated using the JADAD scale and given 4 out of 5 points.

In Lund et al.'s prospective randomized controlled single-blind study conducted with 47 pregnant women whose gestational ages ranged between 22 and 36 weeks in Sweden (2006), among the women participating in the acupuncture group, those who had pain underwent acupuncture application for 30 minutes twice a week for 5 weeks.[22] To assess the severity of the pain of the participants, VAS and the Nottingham Health Profile (NHP) were used. At the end of the study, acupuncture was found to be effective in reducing pain. The study was rated using the JADAD scale and given 3 out of 5 points.

In Elden et al.'s double-blind controlled study conducted with 107 pregnant women suffering from pelvic girdle pain (2008), the data were collected using a Questionnaire (demographic data), VAS, the European Quality of Life 5 Dimensions Questionnaire (EQ-5D), the European Quality of Life health instrument (EQ-5D VAS) and the Oswestry Disability Index (ODI). At the end of the study, the severity of the pain experienced by the participants in the standard care group who did home exercises to strengthen the muscles in the abdominal and gluteal region and the participants in the acupuncture group who underwent 12 sessions of acupuncture treatments, each of which took 30-minutes, twice a week for 4 weeks and once a week for 4 weeks did not decrease significantly in comparison to the participants in the control group.[28] The study was rated using the JADAD scale and given 5 out of 5 points.

In Bishop et al.'s prospective randomized single-blind study conducted in the UK with 91 pregnant women whose gestational ages ranged between 13 and 31 weeks (2006), it was reported that acupuncture reduced pain, but the effect of acupuncture on pregnancy-related LBP and PGP should be clarified by conducting long-term studies.[29] In Bishop et al.'s study, the data were collected using ODI, the Pelvic Girdle Questionnaire (PGQ), EuroQoL EQ-5D-5L, SF-12 and the Numerical rating scale (NRS). The study was rated using the JADAD scale and given 5 out of 5 points.

In Nicolian et al.'s prospective randomized control study conducted with 199 pregnant women (2019), acupuncture needles were kept inserted in place in the treatment group for 30 minutes during each treatment session. The participants underwent 5 sessions, 2 of which were performed in the first week. In the following 3 weeks, 1 session was performed during each week. The participants also received standard care (pregnancy belt, lifestyle recommendations, exercises and painkillers if necessary).[24] the data were collected using NRS, VAS and the Oswestry Disability Self-Questionnaire (OSW). At the end of the study, acupuncture was determined to be effective in reducing pregnancy-related pelvic pain and lower back pain. The study was rated using the JADAD scale and given 3 out of 5 points.

DISCUSSION

Our systematic review in which the effectiveness and reliability of body acupuncture on pregnancy-related pelvic girdle pain and lower back pain was assessed is expected to contribute to the literature with its results. The review consists of four parts: identification, inclusion, data extraction and data synthesis. In our study, we reviewed 6 randomized controlled trials. These RCTs were rated using the JADAD scale. According to the JADAD scale assessments, two studies received 5 out of 5 points, one study received 4 out of 5 points, and 3 studies received 3 out of 5 points.

In this review, the studies in which both lower back pain and pelvic girdle pain were examined were included. Normally, lower back pain and pelvic girdle pain are health problems which have clinically different origins and whose prognosis and treatment in women differ from those in men.[30-32] However, the prognosis and intervention patterns of lower back pain and pelvic girdle pain in pregnancy are similar,[12] and in many studies, they are investigated together.[15,33,34] Therefore, we investigated body acupuncture intervention in pregnancy-related lower back pain and pelvic girdle pain.

Acupuncture is an alternative form of treatment that involves inserting very thin needles into strategic points of the body at various depths. Acupuncture is applied in two ways: body acupuncture and ear acupuncture.[35] Acupuncture is most commonly used in pain relief therapies.[36,37] However, there are studies showing that it is also used in different clinical symptoms and diseases.[38,40]

In this study, we only reviewed randomized

controlled trials conducted on the body acupuncture method. Among the reviewed studies, Elden et al.'s (2008) and Bishop et al.'s (2016) studies which received 5 out of 5 points from the JADAD scale were quite adequate. In their systematic review conducted in 2008 on the effects of acupuncture on pregnancy-related pelvic girdle pain and back pain, Ee CC et al. reported that Elden et al.'s study (2005) had a good evidence level.[41] In the aforementioned study of Elden et al. (2005), pregnant women were divided into 3 groups as the acupuncture, exercise and standard treatment groups. The women in the acupuncture group received acupuncture application on multiple acupuncture points (GV 20, LI 4, BL26, BL32, BL33, BL 54, KI 11, BL 60, EX 21, GB 30, SP12, ST 36) 2 times a week for 6 weeks. The data were assessed by using VAS. As a result of the study, it was determined that the pelvic girdle pain of the women in the acupuncture group decreased substantially in comparison to those in the exercise and standard treatment groups. Elden et al.'s study was rated 4 out of 5 in our review.

In our review, we noticed that, in particular, the studies by Elden et al. (2008) and Bishop et al. (2016) were well-planned and managed. In the results of these two studies, the effect of body acupuncture on pain was described clearly and comprehensibly.[28,29]

In Elden et al.'s (2008) study, pregnant women were divided into two groups are standard treatment + penetrating sham acupuncture and standard treatment + non-penetrating sham acupuncture. In the study, on women in the experiment group, penetrating sham acupuncture application was made for 30 minutes in each session 2 times a week for 4 weeks and 1 time a week for another 4 weeks on multiple acupuncture points (BL 26, 28, 32, 33, 54, 60, GV20, LI4, GB 30, EX 21, KI 11, ST36). The control group received standard treatment + non-penetrating sham acupuncture. The data of the study were analyzed by using VAS, EQ-5D, EQ-5D VAS and ODI. At the end of the study, it was found that the pain and morbidity levels in the women in the experiment group significantly decreased.[28]

In the study by Bishop et al. (2016), pregnant women were divided into 3 groups as the standard care + true acupuncture, standard care + non-penetrating acupuncture and standard care only groups. In the study, in women in the standard care + true acupuncture group, application was made for 30 minutes for 6 weeks on multiple acupuncture points (BL 23, BL 24, BL 25, BL 26, BL 27, BL 28, BL 54, BL 31, BL 32, BL 33 GB 30, HJJ L4, HJJ L5, GB 34, ST 36, LR 3, LI 4, BL 60, BL 62). Application was also made on women in the standard care + non-penetrating acupuncture group for 30 minutes for 6 weeks. The control group received standard care in 2 to 4 sessions for 6 weeks. The data of the study were analyzed using the Oswestry Disability Index, PGQ, EuroQol EQ-5D-5L, SF-12 and NRS. The study by Bishop et al. reported that, although acupuncture applied for LBP and PGP did not have any side effects, the effectiveness of acupuncture could be more clearly understood in long-term studies to be conducted.[29] This is why the results of their study were not as clear as those reported by Elden et al. in 2005 and 2008. As a reason for this it may be considered that other implementations made alongside acupuncture may have been confounding factors on complete analysis of the effect of acupuncture.

The CONSORT checklist is an important criterion in assessment of the quality of randomized controlled trials.[42] We reviewed the studies within this framework. One of the studies we reviewed was Kvorning et al.'s (2004) prospective randomized open study.[4] The study by Kvorning et al. (2004) was one of the oldest studies conducted on this topic. While VAS was used to analyze the data in the study, acupuncture application was made on the LR3, GV20, local tender points 1 or 2 times a week from the 24-37th week of pregnancy until delivery.[4] Kvorning et al. (2004) compared the acupuncture group to the control group that did not receive an additional treatment or sham stimulation. In their study, the pain suffered by the women in the acupuncture group was reported to be lower than was that suffered by the women in the control group, but we decided that this study was not strong enough because there was no other intervention group. Similarly, in another systematic review examining the same study, the study was not considered strong enough for the same reason.[41] Likewise, in Lund et al.'s (2006) study and Nicolian et al.'s (2019) study, there was only one intervention group and a control group each. Lund et al. (2006) used VAS and NHP to assess the data of their study, and application was made for 30 minutes 2 times a week on women in their 22-36th week of pregnancy on multiple acupuncture points (BL 27, 28, 31, 32, 54, KI11, CV3, SP 6, LR 2, LI4). The intervention made on

the women in the control group was unclear. As a result of the study, the LBP of the women was determined to decrease.[22] Nicolian et al. (2019) analyzed the data in their study by using NRS, the Oswestry Disability Self-Questionnaire—OSW and VAS. Application was made on the women in the control group on 3 different acupuncture points (40V, Weizhong and A Shi points) 2 times in the first week and 1 time in each of the following 3 weeks in addition to standard care. The control group received standard care only. As a result of the study, it was determined that acupuncture was an effective method in reducing pelvic girdle pain and lower back pain.[24]

The different aspect of the studies by Nicolian (2019) and Kvorning (2004) in comparison to the other studies we reviewed was that they applied acupuncture applications on only 3 different acupuncture points once a week and reported that it was a highly effective method in reducing PGP and LBP. There was no other intervention group. In both of these studies, acupuncture was found to be an effective method in reducing pregnancy-related pelvic girdle pain and lower back pain.[4, 24] These studies were not strong enough, because there was no other intervention group.

Limitations

Two of the 6 studies we reviewed in our systematic review were quite adequate and provided strong evidence to the literature. While it was a strength of our review that the assessment of the studies was conducted using the JADAD scale, many studies conducted on this topic that were in Chinese were excluded from the review due to the inclusion criteria allowing articles written in English and Turkish, which was a limitation of our review. On the other hand, it was noteworthy that the studies included in our review which were carried out in various countries of Europe were designed quite well.

While screening the databases, we noticed that, in studies investigating the effects of acupuncture on reducing pregnancy-related pelvic girdle pain and lower back pain, body acupuncture was used more commonly than ear acupuncture. Therefore, we reviewed only studies on body acupuncture, which limited the number of studies we reached. Therefore, the finding that body acupuncture reduced the symptoms of pelvic girdle pain and lower back pain in the studies included in our systematic review cannot be generalized.

CONCLUSION

According to the results of the studies we reviewed, body acupuncture is a non-pharmacological method that is effective in reducing lower back and pelvic girdle pain arising in pregnancy. We hope this review will help clinicians and provide significant information for patients and healthcare professionals on body acupuncture as a non-pharmacological method used to relieve the symptoms of pregnancy-related pelvic girdle pain and lower back pain.

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Author contributions: Conceptualization: [ND]; Design: [ASK, ND]; Writing: [ASK, ND, SDA]; Investigation/Data collection: [ASK, ND, SDA]
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