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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.

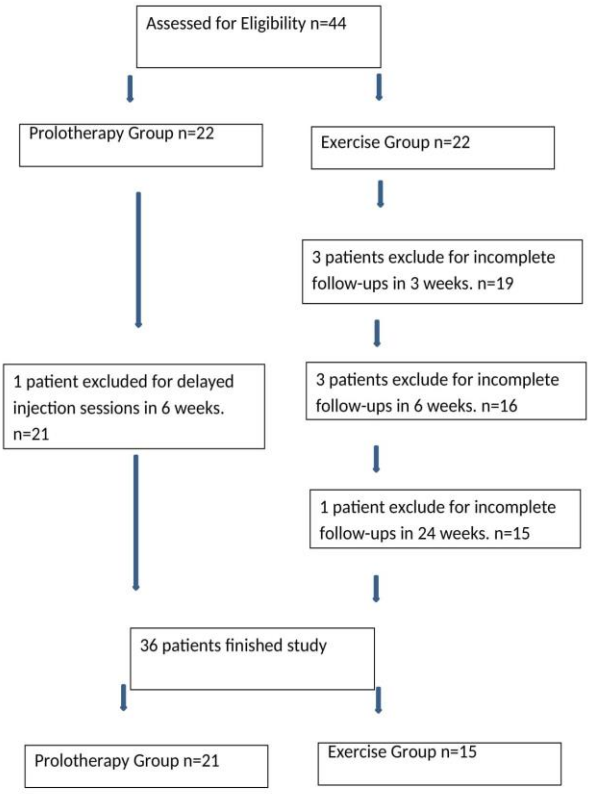

Figure 1. Flowchart of the study.

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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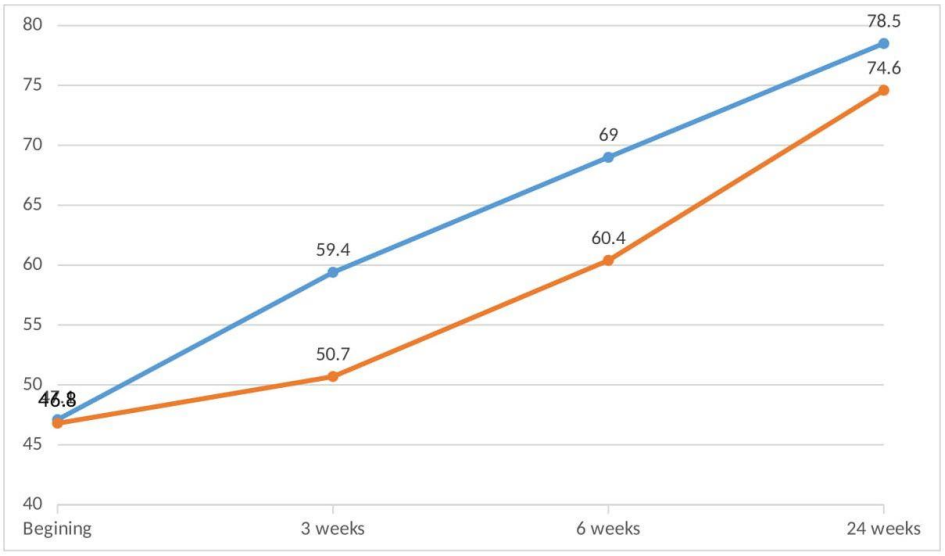

Figure 2. Lower extremity functional scores (LEFS) of the groups. Blue line for the prolotherapy group and orange line for the exercise group

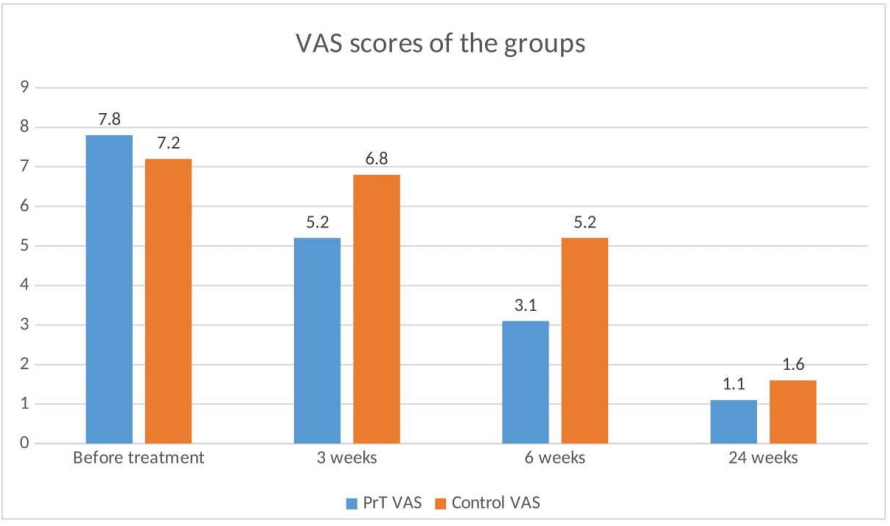

Figure 3. VAS scores of the groups

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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