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Comparison of efficacy of platelet-rich plasma and extracorporeal shock-wave therapy on pain and functional capacity in patients with Plantar Fasciitis

Plantar Fasiit Hastalarında Trombositten Zengin Plazma ve Ekstrakorporeal Şok Dalga Tedavisinin Ağrı ve Fonksiyonel Kapasite Üzerine Etkisinin Karşılaştırılması

Ümit Yalçın[1*]

[1]*Medicana International İstanbul Hospital, Department of Physical Medicine and Rehabilitation, İstanbul, Turkey.*

ABSTRACT

Aim: Plantar Fasciitis (PF) is one of the most common causes of heel pain. There are various conservative methods for the treatment of PF. Nearly 10% of the patients are refractory to the conservative methods and thus undergo surgical procedures. This study aimed to compare the efficacy of platelet-rich plasma (PRP) injection with that of extracorporeal shock-wave therapy (ESWT) in PF patients.

Patients and Methods: The study included 58 patients (40 females), who had complaints for at least 3 months and were refractory to the non-steroidal anti-inflammatory drugs and stretching exercises. The patients who underwent PRP injection (n=29) and ESWT (n=29) were evaluated regarding pain severity by Visual Analogue Scale (VAS) and functionality by Foot Function Index (FFI) both before and at the 3rd month after treatment.

Results: In both groups, a significant improvement was observed in the VAS and FFI scores at the 3rd month after the treatment as compared with the pretreatment scores. The improvement in the VAS and FFI scores was significantly greater in the PRP group than in the ESWT group ($P < 0.05$).

Conclusions: PRP can be a more effective method than ESWT in improving pain and functional scores in PF patients. However, further studies are needed on this issue.

Keywords: Platelet-rich plasma, Plantar Fasciitis, extracorporeal shock-wave therapy, pain, injection, therapy, foot joints, complementary medicine

ÖZ

Amaç: Plantar fasiit (PF), topuk ağrısının en sık görülen nedenlerinden biridir. PF tedavisi için çeşitli konservatif yöntemler vardır. Hastaların yaklaşık% 10'u konservatif yöntemlere dirençlidir ve bu nedenle cerrahi işlemlere tabi tutulur. Bu çalışmada PF hastalarında trombositten zengin plazma (PRP) enjeksiyonunun ekstrakorporeal şok dalgası tedavisinin (ESWT) etkinliği ile karşılaştırılması amaçlandı.

Hastalar ve Yöntemler: Çalışmaya en az 3 aydır şikayeti olan ve steroid olmayan antienflamatuar ilaçlara ve germe egzersizlerine direnç gösteren 58 hasta (40 kadın) alındı. PRP enjeksiyonu (n = 29) veya ESWT (n = 29) uygulanan hastalar, tedavi öncesi ve tedaviden sonraki 3. ayda, Ağrı şiddeti, Görsel Analog Skala (VAS) ve İşlevsellik ise, Ayak Fonksiyon İndeksi (FFI) ile değerlendirildi.

Bulgular: Her iki grupta da, tedavi sonrası 3. ayda VAS ve FFI skorlarında tedavi öncesi skorlara göre anlamlı bir iyileşme gözlendi. PRP grubunda VAS ve FFI skorlarındaki iyileşme ESWT grubuna göre anlamlı olarak daha yüksekti ($P < 0.05$).

Sonuç: PRP, PF hastalarında ağrı ve fonksiyonel skorları iyileştirmede ESWT'den daha etkili bir yöntem olabilir. Ancak, bu konuda daha fazla çalışmaya ihtiyaç var.

Anahtar kelimeler: Trombosit bakımından zengin plazma, Plantar fasiit, ekstrakorporeal şok dalgası tedavisi, ağrı, enjeksiyon, tedavi, ayak eklemleri, tamamlayıcı tıp

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* **Corresponding Authors:** Ümit Yalçın. Medicana International İstanbul Hospital, Department of Physical Medicine and Rehabilitation, Beylikdüzü, İstanbul, Turkey: Phone: +905074372973 e-mail: drumitftr07@gmail.com

ORCİD: 0000-0003-4799-2759

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INTRODUCTION

Plantar Fasciitis (PF) is known as the most common cause of heel pain in adults. PF accounts for nearly 80% of the heel pain in people. Moreover, it has been found that one of each ten people experiences heel pain at some point during their lives [1].

The most widely accepted opinion regarding the etiology of PF is that PF is not an inflammation but a degenerative process due to myxoid degeneration, micro lacerations, collagen necrosis, and angiofibroblastic hyperplasia resulting from repetitive microtraumas, particularly at the calcaneal attachment point of the Plantar fascia [2]. The pain typically occurs in the morning and/or with the first step after sitting for a long time and causes difficulties in performing the activities of daily living [3]. The diagnosis is usually established based on the clinical history and the signs of local tenderness.

PF is frequently a self-limiting disorder. Complaints disappear in 10 months in 80-90% of the cases. Nevertheless, the process can be problematic for both patients and physicians. Depending on the natural course of the disease, the choice of treatment is usually non-surgical therapeutic options [4]. Conservative methods, including non-steroidal anti-inflammatory drugs (NSAIDs), heel cushions or orthoses, physical therapy, stretching exercises, corticosteroid injection, and extracorporeal shock-wave therapy (ESWT), form the basis of PF treatment and provide significant relief in nearly 80% of the patients [5].

ESWT has brought a new dimension to the treatment of PF. In the year 2000, the US Food and Drug Administration (FDA) approved the use of a ESWT device, which is an electro-hydraulic device, in the treatment of chronic PF [6]. Shock-wave modalities can create rapidly rising acoustic waves by their high peak-pressure amplitudes and most of the energy flow is concentrated on a small focus [3]. Pain, redness, edema and ecchymosis are quite rarely reported during ESWT procedure and are not permanent. The exact mechanism of action of ESWT remains unclear. However, it is thought to act by stimulating the repair process of the body and by enhancing healing ability in the relevant region.

In the treatment of PF, ESWT shows its efficacy over the biological mechanisms by destroying unmyelinated sensory nerve fibers and thereby initiating the neovascularization process in the degenerative tissues. Previous studies have reported that ESWT stimulates secretion of local growth factors and accelerates intrinsic wound healing processes such as selection of suitable stem cells [5].

Today, another non-surgical therapeutic option for PF is the platelet-rich plasma (PRP) injection. PRP is a treatment modality that stimulates natural healing steps via the growth factors in platelets. PRP applied to a wound site accelerates healing process, provides support for cellular binding, reduces pain, and has anti-inflammatory and anti-bacterial effects [7]. In the literature, there are studies investigating the use of PRP in the treatments of PF and chronic tendinopathy. In addition to the ready-to-use kits, PRP can be obtained also manually from the peripheral blood.

Nevertheless, many questions about the PRP procedure such as ideal volume, frequency of application, and platelet activation have remained unanswered [8]. Thus, the present study aimed to investigate the effects of ESWT and PRP injections which have been frequently used in recent years for the treatment of PF patients on pain and physical functioning.

The present study included patients who were admitted to the Physical Medicine and Rehabilitation Outpatient Clinic between January 2018 and July 2018, diagnosed and followed-up with PF, and refractory to the first-line conservative treatment consisting of NSAIDs and stretching exercises performed for at least three months.

The patients were randomly (sealed envelope) divided into two groups to undergo PRP injection or ESWT. The diagnosis of PF was established based on clinical examination and plain radiographies of the patients were reviewed to distinguish other pathologies of the heel.

Exclusion criteria were as follows: presence of systemic diseases, pregnancy, presence of active tumor or hematological malignant disease, presence of infection, history of anticoagulant use, receiving NSAIDs within the past 5 days,

a hemoglobin level of <11 g/dL, a platelet count of <150,000/mm3, history of previous steroid injection into the heel region, presence of a previous calcaneus fracture, or history of previous surgery of the heel region.

The study was approved by the Institutional Review Board of Medicana International Istanbul Hospital (IRB 01-2018-005). All patients were informed about the study procedures, their consents were obtained and the patients' personal rights were protected over the study period by following the Helsinki Declaration.

Platelet-rich plasma injection and extracorporeal shock-wave therapy procedures:

Preparation and application of PRP were performed under the same conditions in all patients. A total of 10 mL of peripheral blood was drawn from the antecubital vein into the tubes containing 3.2% sodium citrate. The blood samples were centrifuged at 3200 rpm for 10 minutes at room temperature using an Eppendorf® centrifuge 5702 device (Hamburg, Germany).

The obtained 2 mL of PRP was administered under sterile conditions into the most sensitive point determined by palpation in the medial region of the foot. After PRP administration, the patients were placed in the supine position for 20 minutes. Each patient was informed that the pain would probably increase for the next three days. Ice application was recommended on the painful region for 10 minutes 3 times a day. In addition, the patients were asked not to receive NSAIDs for one week as they are likely to interfere with platelet activity. Additional treatments, such as orthoses (for example heel cushion) were not performed until the end of the study. PRP injection was performed 3 times with 1-week intervals.

In the ESWT group, ESWT was performed on the region where the pain was the most intense using the BTL-6000 SWT device (BTL Industries Ltd., Hertfordshire, UK) with a frequency of 15 Hz, at a pressure of 2 bars, and with 2 500 pulse/session. This procedure was performed once a week for three weeks (three sessions). The patients in the ESWT group were also recommended to apply ice in the presence of pain. Additional treatments, such as orthoses and heel cushions, were not performed until the end of the study.

All patients in both groups were provided with a six-week exercise program. This program consisted of stretching exercises for the gastrocnemius and soleus muscles and the Plantar fascia. The exercises were performed under the supervision of the same clinician as 15 repetitions each for 10 seconds and twice a day. The patients were evaluated both before and 3 months after the treatment using the Visual Analog Scale (VAS) for pain and the Foot Function Index (FFI) for functional status.

Pain Assessment:

For pain assessment, the pain felt during the first few steps in the morning was evaluated using the VAS. A 10 cm non-segmented line was used to assess the pain severity. It was explained to the patient that 0 corresponds to no pain and 10 corresponds to unbearable pain. The patients were asked to mark the point on the non-segmented line indicating the severest pain felt during the first few steps in the morning and the values were recorded in the patient's follow-up form.

Functional Assessment:

Functional assessment was performed using the FFI which is used for foot problems affecting foot functions. The FFI is a questionnaire consisting of 23 items divided in to 3 subcategories (5 items in the activity limitations subcategory, 9 items in the pain severity subcategory and 9 items in the disability subcategory). Each item was evaluated by marking on a 10-cm horizontal line according to the VAS and was rated between 0 and 100. The arithmetical mean of all scores was calculated: higher average scores indicated higher pain, disability and activity limitation [9]. The Turkish translation and adaptation of the FFI was performed by Yalıman et al [10].

For both VAS and FFI, values were recorded at the beginning of treatment and 3 months after the end of treatment

Statistical Analysis:

Data analysis was performed using the IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA) and the normality of the

data was tested using the Kolmogorov-Smirnov test. Descriptive statistics were expressed as mean, standard deviation, median, minimum and maximum, and number and percentages, where appropriate. The independent samples t-test and the Mann-Whitney U test were used to compare quantitative data. The Wilcoxon test was used for the analysis of repeated measurements and the chi-square test was used to compare qualitative data. A P value of <0.05 was considered statistically significant.

RESULTS

The present study included 58 patients with PF (40 females and 18 males) who were divided into two groups as those undergoing PRP injection (PRP group; n=29) and those undergoing ESWT (ESWT group; n=29). The mean age of the PRP group (20 [69.0%] females and 9 [31.0%] males) was 47.4±11.1 years (median, 48.0 years) and the mean age of the ESWT group (20 [69.0%] females and 9 [31.0%] males) was 49.9±8.2 years (median, 49.0 years). The study groups were similar in terms of age (P = 0.337) and sex (P = 1.000) distribution. None of the patients developed local or systemic complications during or after the procedures (Table 1).

The VAS and FFI scores of the PRP and ESWT groups, before and after treatments as well as the change in the scores from pre- to post-treatment, are presented in Table 1. No significant difference was determined between the groups in terms of pre-treatment VAS scores (P >0.05).

The mean VAS score was observed to be significantly decreased from pre to post-treatment, both in the PRP (P <0.05) and ESWT groups (P <0.05). The mean post-treatment VAS score was significantly lower in the PRP group than in the ESWT group (P <0.05). The decrease in the mean VAS score from pre to post-treatment was significantly higher in the PRP group than in the ESWT group (P <0.05).

The PRP and ESWT groups did not differ in terms of pre-treatment FFI scores (P >0.05). The mean FFI score was observed to be significantly decreased from pre to post-treatment both in the PRP (P <0.05) and ESWT (P <0.05) groups. The mean post-treatment FFI score was significantly lower in the PRP group than in the ESWT group (P <0.05). The decrease in the mean FFI score from pre to post-treatment was significantly higher in the PRP group than in the ESWT group (P <0.05) (Table 1).

Table 1. Visual Analog Scale scores and Foot Function Index scores of the study groups

		PRP Group		ESWT Group		P
		Mean±s-d/n-%	Median	Mean±s-d/n-%	Medi-an	
Age		47,4 ±11,1	48	49,9 ±8,2	49	0,337t
Gender	Fe-male	20/ 69,0%		20/ 69,0%		
	Male	9/ 31,0%		9/ 31,0%		
Visual Analog Scale (VAS)						
Pre-Treatment		6,6±1,3	7,0	6,4±1,4	7,0	0,594m
Post-Treatment (3 Month)		2,0±1,6	2,0	3,5±1,5	4,0	0,001m
Post-Treatment Change		4,7±2,1	5,0	2,9±1,4	3,0	0,001m
Difference Intra Group p		0,000	w	0,000	w	
Foot Function Index (FFI)						
Pre-Treatment		69,0±12,9	70,8	66,9±16,1	69,8	0,675m
Post-Treatment (3 Month)		21,7±16,8	21,6	36,3±17,5	40,0	0,006m
Post-Treatment Change		47,3±20,4	50,0	30,6±17,8	32,0	0,005m
Difference Intra Group p		0,000	w	0,000	w	

[t] t test / [m] Mann-Whitney u test / [X²] Chi-square test / [w] Wilcoxon test

PRP, platelet-rich plasma; ESWT, extracorporeal shock-wave therapy; SD, standard deviation; VAS, Visual Analog Scale; FFI, Foot Function Index.

DISCUSSION

Plantar Fasciitis, which is the most common cause of heel pain in adults, appears in one of each 10 people at some point during their lives and the sooner the treatment is started the faster it improves. PF has been reported to be more prevalent in females, overweight individuals, and young male athletes [5]. In the present study, the percentage of female patients (69%) was also higher.

In the literature, it has been reported that PF occurs at the age of 25-64 years and is most frequently

seen at the age of 40-60 years [1]. In the present study, the mean age was 48.7±9.8 years and was in line with those reported in the literature.

Treatment of PF consists of two groups of approaches as conservative and surgical treatments [11]. Nevertheless, there is a remarkable consensus on the fact that non-surgical techniques would be sufficient in 70-90% of the patients with heel pain [5,11]. The first-line treatment protocol includes the following, in order of use: resting and activity modification, cold compress, stretching techniques, NSAIDs, heel cushions and insoles, and weight loss [2]. In case sufficient improvement could not be achieved in 6-8 weeks, a second-line treatment, including physical therapy implementations (strengthening exercises, iontophoresis, deep myofascial massage), injection therapies (steroids, dextrose, botulinum toxin, PRP), ESWT, dry needling and night splints, is used after the diagnosis is confirmed using imaging methods [12]. Plantar fasciotomy is recommended for persistent PF, which is refractory to conservative therapies and complaints of which last for longer than 6 months [1]. There are numerous non-surgical treatment options with different success rates in the treatment of PF, yet there is currently no consensus on the ideal choice of treatment for PF.

In recent years, PRP and ESWT have been increasingly used for the treatment of the pathologies of foot and ankle. The present study was designed to compare the efficacy of PRP injections with that of ESWT in the treatment of chronic PF. Accordingly, 3-dose PRP injections in the treatment of PF was determined to be more effective than 3-sessions of ESWT in terms of pain and functional outcomes.

The average platelet concentration of whole blood is 200,000 per µl (normal range 150,000–350,000 per µl). Platelets are small anucleated cytoplasmic fragments of megakaryocytes that are commonly thought of as the responsible agents for hemostasis. Although the platelet is central to the coagulation cascade, it is also essential to tissue healing. The first step of the healing process is clot formation and platelet activation. Many growth and differentiation factors are released from the α-granules, which are the storage units found in platelets. 95% of the existing factors are released within 10 min of clot formation, whereas the rest of the growth factors are released as they are formed over several days. In vivo and in vitro researches also suggest that PRP induces over expression of additional endogenous growth factors, beyond what is contained within the platelet concentrate [13,14]. PRP activates the circulating regenerative cells by stimulating various types of cells in the tissues [15]. There are more than 30 bioactive proteins in the alpha granules of the platelets. Growth factors in PRP such as platelet-related growth factors, transforming growth factor, vascular endothelial growth factor and insulin-like growth factor, as well as proteins in PRP such as fibrin, fibronectin, vitronectin, and thrombospondin, play a role in many steps of tissue healing [10]. Growth factors provide soft tissue healing and bone regeneration by activating some cells that play a role in tissue healing. With the effects of growth factors which blood includes, PRP stimulates the local stem cells and activates the regenerative cells in the bone marrow through blood circulation. In addition, regarding tendon healing, PRP enhances tenocyte proliferation in the healing site by providing revascularization via the growth factors it includes and plays an effective role in enhancing collagen expression in the tenocytes [16].

PRP can be obtained either as ready-to-use kits or manually. In a vitro study, it was stated that a thrombocyte concentration 2.5 times higher than the basal thrombocyte count would be the most effective [17]. A prepared PRP sample is activated with the addition of bovine or human thrombin or calcium chloride. Growth factors and cytokines are released from the activated PRP with the formation of thrombocyte gel. In some previous studies, PRP has been used without activating. There is no consensus on the ideal volume, frequency of application or thrombocyte activation in PRP procedure [8]. Martinelli et al. applied PRP treatment to 14 patients with PF at 1-week interval, 3 sessions in total and found improvement in pain and functional scores in all patients after 12 weeks [18]. In the present study PRP injection was performed 3 times with 1-week intervals, prepared using a ready-to-use kit (S&M PRP kits, STR Biotechnologies Co. Ltd., Çorum, Turkey). The analysis of the prepared PRP

sample using this kit revealed a 5-times higher platelet concentration than that in the peripheral blood and calcium chloride was not added into this preparation for activation.

Extracorporeal shock-wave therapy has been used for the last decade in the treatment of chronic PF. It is a debatable method of treatment, despite the presence of numerous studies supporting its clinical efficacy, as neither the underlying mechanism of therapeutic efficacy nor the most appropriate treatment protocol has been completely identified yet [19]. Extracorporeal shock wave therapy (ESWT) is a noninvasive procedure used in rehabilitation therapy that is recently being applied in the treatment of tendinopathies and Plantar Fasciitis as well [20]. In ESWT, shock waves are generated by means of electrohydraulic, piezoelectric and electromagnetic methods. There are some possible mechanisms mentioned for the efficacy of shock wave therapy: the transmitted waves may have effects on physiology of pain receptor and also, through microtrauma, they may initiate healing processes by the release of molecular agents and growth factors leading to neovascularization [21]. Despite increasing use of ESWT in the treatment of Plantar Fasciitis, few well-controlled trials have been conducted to approve its efficacy.

Considering the potential complications of both steroid injection and surgical treatment after conservative therapy, ESWT is a therapy that can be easily tolerated by patients [22]. There is, as of yet, no standard procedure for ESWT in the treatment of PF, such as intensity of energy, number of pulses, frequency of sessions and mode of administration. In different applications, the dose changes between 0.02 mJ/mm2 and 0.36 mJ/mm2 and the number of pulses changes between 1 000 and 4 000. It has been reported that a single session is performed at high energy intensity and three sessions are performed at moderate-low energy intensity [1].

In the present study, a total of three sessions of ESWT was performed at a dose of 2 000 pulse/ sessions in one-week intervals. Success rate of ESWT in the treatment of PF ranges from 57% to 88% [1]. Aqil et al. conducted a meta-analysis of seven different randomized controlled trials including a total of 663 participants (369 in the placebo group and 294 in the ESWT group) to investigate the efficacy of ESWT in the treatment of chronic PF [23]. They suggested that ESWT was an effective therapy as compared with the placebo and could be used in patients not benefiting from conservative therapy. In the present study, pain and functional status were also significantly improved in the patients receiving ESWT.

There is a limited number of studies in the literature comparing PRP and ESWT in the treatment of PF. In a study by Chew et al. conducted on 54 patients with PF, they determined that PRP injection and ESWT were superior to conventional therapy (stretching exercises of the Plantar fascia) in terms of pain and functional status during the 1st, 3rd and 6th months of follow-up, with no significant difference between the two methods [24]. Li et al. conducted a meta-analysis of 41 studies comprising a total of 2 889 patients and evaluated the efficacy of 8 different treatment methods used to treat PF (NSAIDs, corticosteroid injection, autologous blood transfusion, PRP injection, ESWT, ultrasound therapy, botulinum toxin A, and dry needling) in terms of VAS scores. They found that only ESWT was superior to placebo in terms of VAS score at the 1st month and that ESWT was again beneficial at the 3rd month. Accordingly, they concluded that ESWT was the optimum therapeutic method in PF patients, whereas botulinum toxin A and PRP injection might be suboptimal therapeutic methods [25].

The present study has some limitations:

The lack of a placebo-controlled group, evaluating the patients based on patient-reported outcomes alone (i.e., function and pain scores), and a relatively short follow-up period could be considered as the limitations of the present study.

In conclusion:

The functional scores significantly increased and the pain scores significantly decreased at the third month, as compared with the pretreatment (baseline) scores in both groups. Comparing the two groups, changes in the functional and pain scores were significantly better in the PRP group than in the ESWT group. None of the patients in either group developed complications. The

present study is one of a limited number of studies comparing PRP with ESWT in the treatment of PF: it is obvious that further large-scale studies are needed to compare the efficacy of these two methods.

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