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ORIGINAL ARTICLES

Clinical Investigations

RADIAL SHOCK WAVE THERAPY FOR PLANTAR FASCIITIS: A ONE YEAR FOLLOW-UP STUDY

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ABSTRACT

The vast majority of published papers on the efficacy of extracorporeal shockwave therapy (ESWT) have come up with rather controversial results in patients with plantar fasciitis. The AIM of the present study was to investigate the effect of radial shock wave therapy in patients with chronic proximal plantar fasciitis.

MATERIAL AND METHODS: Twenty-one patients were included in the study (mean age 51.29 ± 2.02 yrs, mean duration of symptoms 10.14 ± 1.11 mos). Radial shock wave therapy was administered in five sessions. Total number of shocks per session was 2500 at a pressure of 2.5 bars. Visual analog scale (VAS) and a modification of the clinical rating system of the American Orthopedic Foot and Ankle Society (AOFAS) were used for outcome measurement. The patients were assessed before treatment and followed up 3, 6, and 12 months after end of treatment.

RESULTS: Statistically significant improvement in pain and functional capacity was found after completion of treatment in comparison with baseline; the improvement was preserved throughout a one-year follow-up. VAS mean score for pain showed changes in pain while walking the first few steps in the morning from 6.28 ± 0.4 before therapy to 2.85 ± 0.48 after treatment and to 1.52 ± 0.31 at 3 months, to 1.09 ± 0.25 at 6 months, and to 0.52 ± 0.14 at 12 months of follow up ($p < 0.001$). Similar dynamics was observed in pain intensity during daily activities, at rest, in the evening and upon compression. The AFOAS score showed a statistically significant reduction in pain – from 11.90 ± 2.35 at baseline to 31.90 ± 1.48 after the end of interventions ($p < 0.001$), and to 39.52 ± 0.47 at one year of follow-up ($p < 0.001$). The mean values of the evaluation reflecting activity limitations and support requirements increased from 3.85 ± 0.42 to 7.85 ± 0.46 after treatment and to 9.71 ± 0.19 at one year of follow up ($p < 0.001$). Similar dynamics was seen in the maximum walking distance and walking surfaces. Gait abnormalities changed from 3.43 ± 0.50 at baseline to 6.28 ± 0.59 after treatment ($p < 0.001$).

CONCLUSION: Based on the results of this study we could conclude that radial shock wave therapy is a safe non-invasive method of treatment. Our preliminary findings indicate that it could be an effective treatment of choice for patients with chronic plantar fasciitis that is recalcitrant to other conservative treatment modalities.

Key words: *plantar fasciitis, radial shock wave therapy*

INTRODUCTION

In the past decades extracorporeal shock wave therapy has been widely used to treat a number of musculoskeletal disorders. Plantar fasciitis is one of the indications approved by the International Society for Medical Shock Wave Treatment. It is manifested as pain originating from the insertion of the plantar fascia near the medial tubercle of the calcaneus, the pain typically being the most severe while walking the first few steps in the

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morning.[1] Pathophysiologically, it is usually attributed to overuse and ruined foot biomechanics.[2] Treatment of the condition is conservative in 90% of cases. Extracorporeal shock wave therapy is one of the methods used to manage chronic cases with complaints going on for more than 6 months and refractory to conservative methods of treatment.

Extracorporeal shock waves (ESW) are a sequence of single sonic pulses with steep pressure rise (0.01 μsec), high peak pressure (up to 120 MPa, over 500 Bar), followed with a low tensile amplitude (10 MPa), short duration (0.3 μsec), therapeutic effect in the body up to 12 cm. Radial shock waves (RSW), a relatively new modality compared to the focused shock wave therapy, have longer rise time (50 μsec) and pulse duration (200-2000 μsec), significantly lower in peak pressure (0.10 - 1 MPa) and depth of penetration (0-3 cm). The focal point of energy is centred not on the target zone (as it is in focused shock waves), but on the tip of the applicator with radial emission in the tissues.[3,4] In spite of the doubts some authors have about the efficacy of RSWT, the technique offers some advantages especially in disorders in which ESWT of low (~0.08 mJ/mm²) to medium energy (~ 0.28 mJ/mm²) is recommended. The advantages offered by radial shock wave therapy are easy application, no local anesthesia and no ultrasound guide needed, and fewer adverse effects.

There are a lot of studies about the efficacy of focused ESWT in the treatment of plantar fasciitis. A Cochrane review in 2003, updated in 2010, concluded that although ESWT was a safe and, in some studies, a clearly effective treatment option, the evidence for effectiveness of ESWT in treating plantar fasciitis is rather conflicting.[5] Relevant clinical studies have produced contradictory results about the efficacy of ESWT and the clinical relevance of the effect compared with placebo treatment remains controversial. While there are a lot of studies about the effect of focused shock wave therapy, the effect of radial shock wave therapy is the subject of little research.[6-14]

The aim of the present study was to assess the efficacy of radial shock wave therapy in the treatment of chronic plantar fasciitis with one-year follow-up.

MATERIAL

Patients and study procedure

This was an observational study in which each patient served as his own control. It was conducted in the Department of Physical and Rehabilitation Medicine, at the Medical University Hospital, Plovdiv, Bulgaria with a 16-month enrolment phase.

Twenty-one patients with chronic plantar fasciitis previously unresponsive to conservative treatment were studied (mean age, 51.29 ± 2.02 yrs (mean ± SEM), 9 women, 12 men, mean duration of complaints, 10.14. ± 1.11 months).

Inclusion criteria were: duration of complaints (pain and functional limitations) longer than 6 months, no effect of previous conservative treatment (NSAIDs, physical therapy, local corticosteroid or anesthetic injections, orthosis, splints). Patients were excluded if they had a history of coagulation disorders, inflammatory disorders of the upper and lower ankle, malignancy, tendon ruptures in the treatment area, if aged below 18 years and in cases of pregnancy, or presence of pacemaker. The washout phases were designated as at least 6 weeks since the last local corticosteroid injections or physiotherapy treatment and one week after the last intake of nonsteroidal anti-inflammatory drugs.

The patients were recruited to the study on random basis when they actively requested medical treatment because of a long period of complaints, already specified diagnosis of plantar fasciitis and failure of other conservative treatment modalities.

METHODS

Outcome measures

Heel pain was assessed by VAS when taking first steps in the morning, at rest, while doing daily activities, in the evening, pain upon compression on the medial calcaneal tuberosity. We used a 10-cm visual analog pain scale with 0 being no pain and 10 being maximal pain.

We used also part of the AOFAS clinical rating system regarding pain (40 points – no pain; 0 points – severe pain) and function (activity limitations, support requirements, no limitations – 10 points, severe limitations – 0; maximum walking distance 5-0; walking surfaces: no difficulties on any surface – 5, severe difficulties - 0) and also gait abnormality, evaluated by the investigator (8 - none, 0 - marked).[15]

The patients were assessed before administration of RSW therapy, after the end of treatment, and 3 months, 6 months and 12 months after completion of the intervention sessions.

Statistical analysis

A descriptive statistical analysis of the quantitative parameters of mean and standard error (SE) and paired sample t-test for comparing the results before

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and after the treatment were performed. SPSS-17 software package was used. Level of significance of the therapeutic effect - $p < 0.05$. The results are presented as mean score and standard error (mean ± SE).

Radial shock wave therapy

The therapy was conducted using BTL-5000 device (BTL Industries Inc., Columbia, USA) and performed 5 sessions (one per week). The total number of shockwave impulses was 2500 per session, the pressure was 2.5 bars: 500 shockwaves of 10 Hz along the insertion of the plantar fascia and localizing the point of maximum pain; 1000 shockwaves of 10 Hz on the most painful points, 500 shockwaves along the plantar fascia, ending with 500 shockwaves of 15 Hz on the insertion of the plantar fascia.

RESULTS

The analysis of the data showed statistically significant decrease ($p < 0.001$) of mean pain scores (heel pain when taking first steps in the morning, at rest, heel pain while doing daily activities, heel pain in the evening, upon compression on the medial calcaneal tuberosity) obtained immediately after treatment in comparison with baseline data; these results remained the same at the follow-up evaluations at 3, 6 and 12 months. VAS evolves: heel pain when taking first steps in the morning from 6.28 ± 0.4 before therapy to 2.85 ± 0.48 after treatment ($p < 0.001$). The statistically significant improvement in comparison with the initial state was preserved after 3 months - 1.52 ± 0.31, 6 months – 1.09 ± 0.25, 12 months - 0.52 ± 0.14 ($p < 0.001$). Heel pain at rest from 5.04 ± 0.54 before therapy to 2.19 ± 0.42 after treatment, 1.00 ± 0.27 at 3 months, 0.85 ± 0.23 at 6 months and 0.42 ± 0.14 at 12 months; heel pain during daily activities – from 7.23 ± 0.36 before therapy to 2.57 ± 0.45 after treatment, 1.00 ± 0.29 at 3 months, 0.76 ± 0.22 at 6 months and 0.47 ± 0.14 at one year ($p < 0.001$). Similar dynamics was observed with respect to pain in the evening and upon compression on the medial calcaneal tuberosity. The mean pain scores at different points of status check in the study sample are presented in Table 1.

The score of AFOAS clinical rating system showed statistically significant reduction in pain – from 11.90 ± 2.35 before the treatment to 31.90 ± 1.48 after the end of interventions ($p < 0.001$), and 39.52 ± 0.47 at one year of follow up ($p < 0.001$). The mean scores for activity limitations and support requirements increased from 3.85 ± 0.42 before treatment to 7.85 ± 0.46 after treatment and 9.71 ± 0.19 at one year of follow up ($p < 0.001$). There was similar dynamics regarding maximum walking distance and walking surfaces. The gait abnormality observed by the investigator changed from 3.43 ± 0.50 at baseline to 6.28 ± 0.59 after treatment ($p < 0.001$) (Table 2).

Table 1. Mean pain scores by visual analogue scale before and after treatment (n = 21)

VAS	At first steps in the morning mean ± SEM	At rest mean ± SEM	During daily activities mean ± SEM	In the evening mean ± SEM	At compression mean ± SEM
Before treatment	6.28 ± 0.40	5.04 ± 0.54	7.23 ± 0.36	7.57 ± 0.42	7.19 ± 0.47
After treatment	2.85 ± 0.48	2.19 ± 0.42	2.57 ± 0.45	2.19 ± 0.52	1.85 ± 0.53
t	6.01	4.68	10.15	10.86	10.39
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
3 mos after treatment	1.52 ± 0.31	1.00 ± 0.27	1.00 ± 0.29	1.04 ± 0.26	1.28 ± 0.31
t	12.21	7.94	5.46	13.99	13.89
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
6 mos after treatment	1.09 ± 0.24	0.85 ± 0.23	0.76 ± 0.22	1.38 ± 0.47	0.95 ± 0.19
t	12.97	8.14	18.54	10.90	12.67
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
12 mos after treatment	0.52 ± 0.14	0.42 ± 0.14	0.47 ± 0.14	0.42 ± 0.14	0.66 ± 0.18
t	14.34	7.97	17.62	14.31	12.04
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001

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Table 2. Mean scores of pain, activity limitations, walking distance, walking surfaces, gait abnormalities as assessed by AOFAS clinical rating system (n = 21)

AOFAS	Pain score mean ± SEM	Mean score of activity limitations mean ± SEM	Mean score maximal walking distance mean ± SEM	Mean score walking surfaces mean ± SEM	Mean score gait abnormalities mean ± SEM
Before treatment	11.90 ± 2.35	3.85 ± 0.42	2.28 ± 0.34	1.71 ± 0.33	3.43 ± 0.50
After treatment	31.90 ± 1.48	7.85 ± 0.46	4.04 ± 0.28	3.66 ± 0.34	6.28 ± 0.59
t	7.74	9.28	7.40	6,77	7.07
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
3 mos after treatment	35.23 ± 1.11	8.85 ± 0.38	4.61 ± 0.10	4.43 ± 0.20	7.24 ± 0.35
t	11.71	9.59	8.12	9.5	8.77
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
6 mos after treatment	37.61 ± 0.95	9.57 ± 0.23	4.80 ± 0.08	4.61 ± 0.17	7.24 ± 0.35
t	10.95	13.40	8.25	8.99	11.36
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001
12 mos after treatment	39.52 ± 0.47	9.71 ± 0.19	4.86 ± 0.78	4.71 ± 0.16	7.62 ± 0.26
t	11.14	12.47	8.02	8.87	9.64
p	p < 0.001	p < 0.001	p < 0.001	p < 0.001	p < 0.001

DISCUSSION

Plantar fasciitis is estimated to account for 11% to 15% of foot disorders in adults.[16] There are different treatment options and the success rate of non surgical treatment is between 44 and 90%.[5,17]

ESWT produces promising results in cases with chronic plantar fasciitis that have been recalcitrant to other conservative methods of treatment. Published randomized and double-blinded studies provide controversial conclusions regarding clinical relevance of treatment effect of ESWT compared with placebo.[6-14,18] Some of the studies concluding that ESWT is not beneficial in the treatment of plantar fasciitis (e. g. Buchbinder et al.) have some weaknesses in their design – patients did not receive identical treatment, did not focus on the area of maximal pain, analgesic drugs were allowed, pain history as short as 6 weeks.[18] Similar results have been reported by Haake et al.[8] In a randomised double blind control trial, Speed CA et al. concludes that there is no treatment effect of a moderate dose of ESWT in subjects with plantar fasciitis.[19] This controversy arises from researchers using different treatment protocols and different patient selection criteria and devices. The indications for application in chronic disorders with a history of more than 6 months should be observed.

A lot of studies find good results after the application of focused ESWT in patients with plantar fasciitis with success rate ranging from 34% to 88%, which is consistent with our findings.[7,11-14,20,21] Wang et al. studied 79 patients with proximal plantar fasciitis and at one-year of follow-up the overall results were 75.3% complaint free, 18.8% significantly better, 5.9% slightly better and none unchanged or worse.[22] In another study, a group of patients treated with ESWT were compared with a group receiving conventional conservative treatment; the results were 69.1% excellent and 13.6% good results in the study group versus 0% excellent and 55% good results in the control group. The results were preserved at 5 years of follow-up with 11% recurrence in the study group to 55% in the control group.[23,24]

Low energy shock waves also proved to be effective in patients with plantar fasciitis.[13,14] Rompe et al. suggested that three treatments weekly with 1,000 impulses of low-energy shockwave at 0.06 mJ/mm^2 appeared to be an effective therapy for plantar fasciitis with significant alleviation of pain and improvement in function.[14]

Lohrer et al. compared the effect of focused medium energy and radial shock wave therapy and concluded that both had nearly equal efficacy, although there is some evidence for focused SWT to be superior to radial shock wave therapy.[25]

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Our findings are in line with that of Ibrahim et al. who find significant decrease in VAS score from 8.5 ± 0.3 to 0.5 ± 0.1 at 24 weeks from the baseline after the application of two sessions of RSWT of 2000 impulses.[10] We applied three sessions and followed up the results till the end of the first year after the treatment and instead of Roles and Maudsley score we used part of the AOFAS clinical rating system, which is more specific for foot disorders.[10] Similar results are reported by Gerdesmeyer et al, comparing RSWT and placebo treatment with follow up at 6 and 12 months.[6]

Radial SWT has certain advantages over focused SWT and these are the wider effective regions it uses, the less stringent requirements for precise focusing, and no need of adjunct local anesthesia.[26] RSWT is better tolerated and less painful, thus obviating the need for local anesthesia and locating the application at the point of maximum pain according to patient-controlled feedback. Rompe et al. obtained better results without local anesthesia[13] than when using anesthesia in plantar fasciitis patients. Besides making focusing exactly on the most painful point rather difficult, local anesthesia could also interfere with the inflammatory mediated process that is discussed as one of the biological mechanisms of SWT. Important inflammatory mediators that increase blood circulation are repressed.

The beneficial effects of shock wave therapy can be attributed to a controlled microdisruption of the plantar fascia, while preserving the gross structural integrity and biomechanics of the foot. SWT also stimulates the initiation of a healing response and adaptation of tissue biology. Inflammatory mediated process and induction of physiological healing process as a result of SWT is discussed. Shock wave therapy stimulates local metabolism, microcirculation, neovascularisation, induction of growth factors and tissue regeneration. SWT induces a neovascularisation process with an early release of angiogenesis-related markers (vascular endothelial growth factor) at the tendon-bone junction.[27,28] Low energy SWT promotes tendon healing (cell proliferation and tissue regeneration) by inducing the TGF-ß1 and insulin growth factor-1.[29] Increased expression of proliferating cell nuclear antigens and activation of endothelial nitrogen oxide syntase was also registered.[30] The pain-relieving effect is attributed to a gate-control mechanism, damage to the neuron cell, degeneration of sensory nerve fibers, and changes in substance P.[31-35]

The limitations of our study are the small number of participants and the lack of a control group with placebo treatment or any other form of conservative treatment. The preliminary results showed that there is pain reduction and improvement in function as evaluated by VAS and AOFAS scales after the end of treatment sessions in comparison with baseline and these are preserved at one year of follow up. Most of the other studies about the efficacy of radial SWT in plantar fasciitis do not follow the effect at 12 months after completion of treatment.

CONCLUSIONS

Based on the results of this group of patients we could conclude that radial shock wave therapy is a safe non-invasive method of treatment. Our preliminary findings indicate that it could be an effective treatment option for patients with chronic plantar fasciitis recalcitrant to other conservative treatment modalities.

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РАДИАЛЬНАЯ УДАРНО-ВОЛНОВАЯ ТЕРАПИЯ ПРИ ПОДОШВЕННОМ ФАСЦИИТЕ; ПРОСЛЕЖИВАНИЕ В ТЕЧЕНИЕ ГОДА

Е. Илиева

РЕЗЮМЕ

***Введение**: Публикации относительно лечебного действия ударно-волновой терапии при подошвенном фасциите показывают противоречивые результаты.*

***Цель**: Настоящее исследование ставит себе целью проследить эффект радиальной ударно-волновой терапии среди пациентов с хроническим подошвенным фасциитом.*

***Материал и методы**: В исследование включено 21 пациент: их средний возраст 51.29 ± 2.02; средняя давность симптоматики – 10.14 ± 1.11 мес. Применено 5 процедур радиальной ударно-волновой терапии. Общее число импульсов – 2500, давление – 2.5 Bar. Для отчитывания результатов применены визуально аналоговая шкала (VAS) и модификация шкалы Американского ортопедического общества по заболеваниям подошвы и лодыжки (AOFAS). Пациентов прослеживали до и после лечения, на 3-ий и 6-ой мес.*

***Результаты**: Установлено статистически значимое улучшение по отношению к боли и к функциональной активности после лечения. Это состояние сохранилось до конца одногодового периода прослеживания. VAS установила изменения в средних стоимостях боли утром при первых шагах – 6.28 ± 0.31 до лечения, 2.85 ± 0.48 после лечения, 1.52 ± 0.31 – 3-ий мес.; 1.09 ± 0.25 – 6-ой мес.; 0.52 ± 0.14 - 12-ый мес. ($p < 0.001$). Подобная динамика наблюдалась по отношению к боли при ежедневной активности, в покое, вечером и при надавливании. Шкала AFOAS показала статистически значимую редукцию боли: 11.90 ± 2.35 до интервенции; 31.90 ± 1.48 - после интервенции ($p < 0.001$); 39.52 ± 0.47 при прослеживании в течение первого года ($p < 0.001$). Средние стоимости оценки, показывающей ограничения в активности и необходимость в подкреплении, увеличились – 3.85 ± 0.47 - 7.85 ± 0.46 после лечения и соответственно 9.71 ± 0.19 – первый год лечения ($p < 0.001$). Подобная динамика обнаружена по отношению к максимальному расстоянию ходьбы и по отношению к затруднениям при ходьбе по различным поверхностям. Отклонения в походке изменились – 3.43 ± 0.50 - до лечения; 6.28 ± 0.59 после лечения ($p < 0.001$).*

***Заключение**: Наблюдения за этой группой пациентов дают основание сделать вывод, что радиальная ударно-волновая терапия представляет безопасный неинвазивный метод лечения. Предварительные результаты исследования показывают,что эту терапию можно применять как средство выбора у пациентов с хроническими формами подошвенного фасциита, резистентных к другим методам лечения.*

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