2012

Is Radial Extracorporeal Shock Wave Therapy an Effective Treatment for Chronic Plantar Fasciitis in Adults?

Lauren H. Rucker
Philadelphia College of Osteopathic Medicine, laurenru@pcom.edu

Follow this and additional works at: http://digitalcommons.pcom.edu/pa_systematic_reviews

 Part of the Musculoskeletal Diseases Commons, and the Other Rehabilitation and Therapy Commons

Is Radial Extracorporeal Shock Wave Therapy an Effective Treatment for Chronic Plantar Fasciitis in Adults?

Lauren H. Rucker, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

December 16, 2011

ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not radial extracorporeal shock wave therapy (ESWT) is an effective treatment in adults with chronic plantar fasciitis.

STUDY DESIGN: Review of three English language primary studies published between 2008 and 2010.

DATA SOURCES: Two randomized control trials and one cohort study analyzing the effects of radial extracorporeal shock wave therapy on chronic plantar fasciitis were found using the OVID, Medline and Cochrane Databases.

OUTCOMES MEASURED: Each of the three studies measured improvement in pain from baseline after patients were treated with ESWT. Pain levels were quantified using a Visual Analog Scale (VAS). The VAS score assigned by each patient was a subjective pain severity score ranging from 0 (no pain) to 10 (worst possible pain).

RESULTS: The dichotomous data from the Gerdesmeyer et al. study and the Ibrahim et al. study showed statistically significant treatment success rates with the use of extracorporeal shock wave therapy to treat plantar fasciitis pain when compared to the control group, as determined by improvement in Visual Analog Scale scores. The continuous data provided by the Hofling et al. study showed a statistically significant improvement in overall pain, maximum pain, and pain with daily activities after participants received ESWT as compared to their pain levels prior to treatment. The Hofling et al. study did not find the reduction of night pain after ESWT to be statistically significant.

CONCLUSIONS: Gerdesmeyer et al., Ibrahim et al., and Hofling et al. all provided data which showed statistically significant pain improvement following extracorporeal shock wave therapy in adult patients with chronic plantar fasciitis. This improvement was present in all three studies despite varying numbers of extracorporeal shock wave therapy treatment sessions and variable time frames between treatments. In order to maximize the efficacy of ESWT, continued research is needed to determine the optimal number of ESWT treatment sessions and the optimal time frame between treatment sessions.

KEY WORDS: plantar fasciitis, heel pain, extracorporeal shock wave therapy

INTRODUCTION

Plantar fasciitis is a common cause of heel pain in adults and young athletes. The pain associated with plantar fasciitis originates on the plantar aspect of a patient's foot near where the plantar fascia inserts into the medial tuberosity of the calcaneus. Patients with plantar fasciitis often have maximal tenderness to palpation over this point of insertion.[1] Additionally, pain can be recreated with passive dorsiflexion of the foot in some patients.[2] Although a heel spur may also be found with physical examination of the calcaneus, the finding does not provide diagnostic inclusionary or exclusionary significance relating to plantar fasciitis.[1]

Severe pain with initial weight-bearing when first getting out of bed in the morning and pain following a period of decreased weight-bearing during the day are common complaints associated with plantar fasciitis. The pain often improves with continued weight-bearing activities only to worsen again with prolonged weight-bearing, creating a frustrating cycle for people with plantar fasciitis.[1,2]

Plantar fasciitis is the most common cause of heel pain.[2] It accounts for 15% of foot symptoms for which adults seek medical care, and it is estimated that 1 to 2 million Americans are treated for plantar fasciitis annually.[3,4] The peak incidence occurs in people between the ages of 40 to 60 years old, but plantar fasciitis is also frequently diagnosed in athletic groups of younger adults who participate in activities like running and dancing.[1] Because of the high prevalence of plantar fasciitis, Physician Assistants are likely to encounter patients with plantar fasciitis in general practice settings like family medicine as well as in specialties like orthopedics.

One study by Riddle et al. estimated approximately 1 million patient visits per year for the treatment of plantar fasciitis based on treatment information gathered from 1995 to 2000.[5] Other

publications estimate a significantly higher prevalence of plantar fasciitis. A 2009 study done by

J.D. Rompe estimated upwards of 2 million office visits annually related to the treatment of

plantar fasciitis.[2] With different studies having widely varying estimates regarding the number of

people being treated for plantar fasciitis annually, the estimates of healthcare costs also vary

accordingly. One study by Tong et al. estimated the 2007 cost of plantar fasciitis treatment to

third-party payers to be $284 million. The cost estimates of this study were based on

approximately 1 million annual patient cases where specific treatment information could be

attained. These estimates likely underestimate the true annual cost of plantar fasciitis due to the

number of cases where treatment information was not available. Included in the annual cost

estimates were physician office visits, pain medication, exercise counseling, physical therapy and

surgical intervention.[4]

The term plantar fasciitis implies an inflammatory process which can be misleading. Biopsy

samples of the plantar fascia from patients who have had surgery for plantar fasciitis revealed

that the fascia had undergone degenerative changes. In addition to the degenerative changes,

inflammatory changes may or may not be present. This has led some clinicians to prefer the term

plantar fasciosis over plantar fasciitis.[2] While the exact cause of plantar fasciitis is unknown,

there are a number of factors that are thought to increase a person's risk of developing plantar

fasciitis. These factors include obesity, pes planus, pes cavus, long periods of standing, walking

or running on hard surfaces, poor footwear, and limited dorsiflexion.[1]

The first line treatment options in the conservative management of plantar fasciitis include

alternating heat and ice treatments, stretching, physical therapy, massage, orthotics, night splints,

ultrasound, iontophoresis, short term use of NSAIDs, corticosteroid injections, and identifying

and avoiding activities that exacerbate plantar fasciitis.[1,6] Various combinations of conservative

treatment measures are used depending on a patient's symptom severity and duration. These conservative treatment options all play an effective role in treating plantar fasciitis; however, up to 20% of patients have little or no response to conservative treatment after a 6 month period.[3] If conservative treatment measures fail to relieve a patient's symptoms after 6 to 12 months, then the next step in treatment typically involves considering a plantar fasciotomy.[1] Surgical intervention is associated with a long recovery period, and recently, a number of studies have proposed extracorporeal shock wave therapy (ESWT) as a surgical alternative for plantar fasciitis that is unresponsive to conservative treatment measures.[3,6,7]

OBJECTIVE

The objective of this selective EBM review is to determine whether or not, "Is radial extracorporeal shock wave therapy an effective treatment for chronic plantar fasciitis in adults?"

METHODS

The inclusion criteria used for the selection of study participants included a population of patients who were at least 18 years old with a clinical diagnosis of plantar fasciitis. The plantar fasciitis had to be present for a minimum of 6 months and it had to be resistant to conservative treatment approaches for the patients to be able to participate in the studies. The intervention being studied is radial extracorporeal shock wave therapy as it relates to effectiveness in reducing the pain associated with plantar fasciitis. The studies used for this review included two randomized control trials and one cohort study. The randomized control trials, both of which were double-blind studies, compared a treatment group which received extracorporeal shock wave therapy to a visually matched placebo group which received no shock wave transmission.[3,6] The cohort study compared each patient's initial pain level with their pain level after shock wave therapy. This cohort study did not include a placebo group.[7] The primary outcomes looked at in

the three studies selected included severity of pain and pain in relation to normal daily activities.

Table 1 outlines the demographics and characteristics of the studies included in this review.

The author of this review completed a thorough search using OVID, Medline and the

Cochrane Database of Systematic Reviews. The key words used in this search included the

combination of "plantar fasciitis" and "shock wave therapy". Only English language articles

published in peer-reviewed journals between 2006 and 2011 were included. The articles selected

were chosen with a focus on relevant, important outcomes to the patient, also known as Patient

Oriented Evidence that Matters (POEMs). The studies chosen were randomized, controlled

studies that were published after 2006 with a focus on patient oriented outcomes. The excluded

studies were those that were published prior to 2006, due to a previous systematic review

published at this time. Additional exclusion criteria included patients that were under age 18 or

patients with plantar fasciitis for less than 6 months. Statistics reported include *p*-values, number

needed to treat (NNT), relative benefit increase (RBI) and absolute benefit increase (ABI).[3,6,7]

Table 1: Demographics and Characteristics of Included Studies

Study	Type	# of Pts	Age	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
Ibrahim[3], 2010	RCT (double-blind, placebo controlled, randomized trial)	50	26 to 87 y.o.	>18 y.o., diagnosis of plantar fasciitis by PE, hx of 6 months unsuccessful conservative tx, therapy free period of 4 weeks prior to referral	Bilateral plantar fasciitis, ankle/foot dysfunction, foot arthritis, tumor or infection of LE, neurologic abnormalities, nerve entrapment, vascular abnormality, operative tx of heel spur, pregnancy, DM, coagulopathies	0	ESWT – 2 sessions, 1 week apart with 2000 impulses per session

Hofling[7], 2008	Cohort Study	20	30 to 68 y.o.	6 months of plantar fasciitis w/no response to conservative tx, diagnosis confirmed w/PE	Specific exclusion guidelines were not included in paper	1	ESWT – 1 session, 2500 to 3000 impulses
Gerdesmeyer[6], 2008	RCT (double-blind, placebo controlled, randomized trial)	251	Mean age 52 y.o. ± 11.3 yrs	> 18 y.o., hx of 6 months of plantar fasciitis resistant to nonsurgical tx (including 2 pharmacological and 2 non-pharmacological txs), diagnosis confirmed clinically w/PE, pain of ≥5 on all 3 VAS scores, completion of no tx phase	Rheumatic or other systemic inflammatory disease, osteomyelitis, active infection or hx of infection in the treatment area, neurological or vascular insufficiencies, nerve entrapment syndrome, coagulopathies, significant bilateral heel pain, pregnancy	26	ESWT – 3 sessions, 2 weeks apart with 2,000 impulses per session

OUTCOMES MEASURED

The primary outcome measured in all three studies was pain which was quantified through

the use of a Visual Analog Scale (VAS). The visual analog scale is a subjective 10 cm long

horizontal line ranging from a score of zero (no pain) to a score of ten (worst possible pain).

Gerdesmeyer et al. examined the percentage change in the composite VAS score by comparing

the baseline score with the score 12 weeks after the last ESWT treatment and 12 months after the

last ESWT treatment. The composite VAS score in the Gerdesmeyer et al. study was the sum of

3 VAS scores which included the scores the study participant assigned to heel pain with the first

steps of the morning, heel pain while doing activities of daily living, and heel pain with the

application of a Dolormeter. The Dolormeter applied quantifiable local pressure to the heel at the point of maximum tenderness. In addition to the assessment of each participant's composite VAS score, individual VAS scores were also assessed in the Gerdesmeyer et al. study. In the Ibrahim et al. study participants rated their current level of pain with a VAS score at baseline and then again at 4 weeks, 12 weeks, and 24 weeks after treatment. Hofling et al. also used VAS scores to compare baseline pain levels with pain levels approximately 72 days after treatment. In the Hofling et al. study, VAS scores were used to rate overall pain, maximum pain, night pain, and pain with activities of daily living for each participant before and after ESWT treatment.

RESULTS

The results, as they pertain to efficacy of the treatment outcomes measured using VAS scores, were analyzed as dichotomous data in the Gerdesmeyer et al. study and the Ibrahim et al. study. The Hofling et al. study did not provide results that could be converted to dichotomous data.

Gerdesmeyer et al. reported an overall treatment success rate of 61% in the experimental group compared with 42% in the control group 12 weeks after radial ESWT. The Gerdesmeyer et al. study defined successful treatment as a greater than 60% decrease from baseline in at least 2 of the 3 heel pain measurements used to make up the composite VAS score. The overall success rate was statistically significant with a p-value = 0.0020 and a Mann-Whitney effect size (one sided 97.5% lower bound confidence interval) of 0.5937. The relative benefit increase (RBI) was calculated to be 45% and the absolute benefit increase (ABI) was calculated to be 19%. Based on these calculated values, the number needed to treat (NNT) was 6 patients. Clinically, this means that for every 6 patients treated with three sessions of radial ESWT, 1 additional patient had a successful plantar fasciitis outcome compared to the control group (Table 2).[6]

Ibrahim et al. reported a treatment success rate of 92% in the experimental group and a treatment success rate of 4% in the control group 4 weeks after radial ESWT. Successful treatment was defined as a decrease from baseline in mean VAS score greater than 60%. The improvement in mean VAS scores from baseline of the experimental group compared with the control group was statistically significant with a *p*-value of less than 0.001. The relative benefit increase (RBI) was calculated to be 22% and the absolute benefit increase (ABI) was calculated to be 88%. Based on these calculated values, the number needed to treat (NNT) for the Ibrahim et al. study was 2 patients. This is clinically significant in that, for every 2 patients treated with two sessions of ESWT, 1 more patient had improvement in their chronic plantar fasciitis compared to the control group (Table 2).[3]

Table 2. Efficacy of Radial Extracorporeal Shock Wave Therapy in Improving Plantar Fasciitis

Study	Control Event Rate (CER)	Experimental Event Rate (EER)	Relative Benefit Increase (RBI)	Absolute Benefit Increase (ABI)	Number Needed to Treat (NNT)	*p*-value and Confidence Interval (CI)
Gerdesmeyer, 2008	42%	61%	45%	19%	6	*p*-value: 0.002 MW effect size CI: 0.5937
Ibrahim, 2010	4%	92%	22%	88%	2	*p*-value: <0.001 CI: not reported

Additionally, both the Gerdesmeyer et al. study and the Ibrahim et al. study included secondary outcome measures in the form of Roles and Maudsley (RM) score data. Because the Roles and Maudsley score allows patients to subjectively assess quality of life outcomes, it should be noted that ESWT may have a positive impact on a patient's quality of life. This data was presented in a continuous format that could not be converted to a dichotomous format for this review and therefore, this data was not included in this analysis.

The Hofling et al. study provided data in the form of VAS scores determined before

treatment and 72 days (± 15 days) after treatment. This study did not provide a control group. A

p-value of less than 0.05 was used as the cut off for statistical significance in this study. Based on

this, a statistically significant decrease was seen in the VAS scores of the participants after a

single session of ESWT in the categories of overall pain, maximum pain, and pain with activities

of daily living. A decrease in the night pain VAS score had an associated *p*-value = 0.317 which

was not statistically significant (Table 3).[7] The Hofling et al. study did not provide data that

could be converted from a continuous format to a dichotomous format for this review.

Table 3. Changes in VAS Scores with a Single Session of ESWT

Study: Hofling et al., 2008			
	VAS score before ESWT	VAS score after ESWT	*p*-value
Overall Pain	5.5 ± 1.8	3.3 ± 2.7	*p* = 0.001
Maximum Pain	7.7 ± 2.1	4.0 ± 3.9	*p* = 0.008
Pain with Activities of Daily Living	5.3 ± 2.1	2.5 ± 2.6	*p* = 0.018
Night Pain	2.4 ± 2.5	1.3 ± 2.1	*p* = 0.317

Regarding the tolerability and adverse events associated with ESWT, Gerdesmeyer et al.

reported that adverse events included primarily pain or discomfort, but also reported other

infrequent adverse events which included heel erythema, swelling, and numbness. Safety

analysis was done on all patients who received at least one ESWT treatment.[6] Of the 251

participants who received at least one treatment, 33 patients reported at least one of these adverse

events in the experimental group and 10 patients from the control group reported at least one

adverse event.[6] Gerdesmeyer et al. reported that the maximum duration of pain experienced by

participants was 10 minutes and that none of the participants received local anesthesia, despite

local anesthesia being offered. Tolerability was judged by the investigator 12 weeks after the last

treatment of ESWT. In the experimental group, the investigator determined that 93.8% of the

participants had "very good" or "good" toleration of the treatment. In the control group, the investigator determined 90.1% of participants had "very good" or "good" tolerability.[6] All patients who received at least one treatment and subsequent evaluation were included in the intent-to-treat (ITT) population. The data for the ITT patients who had protocol violations was handled using the last value carried forward (LVCF) replacement of missing values. The treatment success rate at 12 weeks was able to be analyzed in 89.6% of patients.[6]

Ibrahim et al. reported that no participant dropped out of the study once randomization had occurred. Out of 50 study participants, pain or discomfort was reported by 3 patients who received ESWT and 2 patients who received the placebo treatment. Additionally, 1 patient who received ESWT reported a brief period of skin reddening after treatment. All patients were able to complete the treatments.[3]

The Hofling et al. study reported that 1 participant did not tolerate the ESWT intervention due to pain and this study responded by completely excluding this participant's information from the study data. No further information confirming or denying any additional adverse events of ESWT was provided by the Hofling et al. study.

DISCUSSION

Extracorporeal shock wave therapy (ESWT) is essentially the delivery of high-pressure sound waves to injured tissue areas and it was initially used in the treatment of nephrolithiasis.[4,7] ESWT has been effective in treating calcific tendonitis of the rotator cuff and humeral epicondylitis. In 2000 the FDA approved ESWT for the treatment of adults with plantar fasciitis for greater than 6 months who were not responding to conservative treatment methods.[7] The use of ESWT is contraindicated in certain situations including near areas of known malignant disease, near bone growth centers when bone growth is incomplete, near areas of infection, near

ischemic tissues in people with vascular disease, and in patients with coagulopathies or taking anticoagulant medication.[8]

Both the Gerdesmeyer et al. study and the Ibrahim et al. study found clinically significant successful outcomes using ESWT. Gerdesmeyer et al. performed 3 sessions of radial ESWT, each 2 weeks apart and then evaluated the outcome of the treatment at 12 weeks and 12 months. Each session of ESWT used 2,000 impulses over the point of maximum tenderness.[6] Ibrahim et al. performed 2 sessions of radial ESWT which were 1 week apart with each session using 2,000 impulses and then evaluated treatment outcomes at 4, 12, and 24 weeks. Although these two studies used varying numbers of ESWT treatment sessions and varying follow-up time periods, they both showed statistically significant successful outcomes in the experimental group compared to the control group. Both the Gerdesmeyer et al. and the Ibrahim et al. studies were similar in terms of the methods used to achieve double-blinding, randomization, and control groups. Participant inclusionary and exclusionary parameters were also similar between the 2 studies. A notable difference between the 2 studies was the larger decrease in VAS scores seen in the control group in Gerdesmeyer et al. study. This larger placebo-effect could potentially be attributable to the variation in sample size between the 2 studies, with data analysis being included on 251 participants and 50 participants in the Gerdesmeyer et al. study and Ibrahim et al. study, respectively. Another potential contributing factor to the difference in success rates seen between the control groups in these 2 studies is the inherent self-limiting nature of plantar fasciitis for the majority of patients.[6]

Hofling et al. performed a single session of ESWT using 2,500 to 3,000 impulses. This study design had several limitations including the lack of a control group and consequently, no blinding of participants or investigators was pursued. Additionally, the Hofling et al. study

included a small sample size of 20 participants making the results difficult to generalize to a larger population.

One general limitation of the 3 studies analyzed was the use of a Visual Analog Scale (VAS). The VAS score each study participant chose was based on a self-assessment of pain and with the subjective nature of pain, this rating method has inherent variability between each participant. Consequently, the use of VAS scores is hard to standardize between different participants and between different studies.

CONCLUSION

The three studies reviewed demonstrate that radial extracorporeal shock wave therapy is an effective treatment for adults with chronic plantar fasciitis who have not been responsive to typical conservative methods of treatment.

Future research will need to further evaluate the optimal number of ESWT sessions, the effectiveness of different quantities of shock waves delivered per ESWT session, and the most effective length of time between ESWT sessions. Given the painful nature of plantar fasciitis, future research on the effectiveness of ESWT on adult patients who have had plantar fasciitis for less than 6 months might be indicated.

REFERENCES

1. Langford CA, Gilliland BC. Chapter 337. Periarticular Disorders of the Extremities. In: Longo DL, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, Fauci AS, eds. *Harrison's Principles of Internal Medicine*. 18th ed. New York: McGraw-Hill; 2011. http://www.accessmedicine.com/content.aspx?aID=9139675. Accessed October 1, 2011.

2. Rompe, JD. Plantar fasciopathy. *Sports Med Arthrosc*. 2009;17(2):100-104.

3. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. *Foot Ankle Int*. 2010;31(5):391-397.

4. Tong KB, Furia J. Economic burden of plantar fasciitis treatment in the United States. *Am J Orthop*. 2010;39(5):227-231.

5. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. *Foot Ankle Int*. 2004;25(5):303-310.

6. Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. *Am J Sports Med*. 2008;36(11):2100-2109.

7. Hofling I, Joukainen A, Venesmaa P, Kroger H. Preliminary experience of a single session of low-energy extracorporeal shock wave treatment for chronic plantar fasciitis. *Foot Ankle Int*. 2008;29(2):150-154.

8. FDA resources page. Food and Drug Administration Web site. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078648.htm. Accessed December 4, 2011.