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Is Extracorporeal Shock Wave Therapy An Effective Treatment For Improving Pain In Adults With Medial Tibial Stress Syndrome?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not extracorporeal shock wave therapy is an effective treatment for improving pain in adults with medial tibial stress syndrome.

Study Design: Systematic review of two randomized controlled trials (RCTs) and a cohort study published in peer-reviewed journals from 2010-2017, all in the English language.

Data Sources: Two randomized controlled trials found through PubMed and a cohort study found through Google Scholar.

Outcomes Measured: Pain was measured using a numerical rating scale (0-10) and visual analog scale (VAS).

Results: Study by Newman et al. (*J Sci Med Sport*. 2017;20(3):220-224. doi: S1440-2440(16)30140-2 [pii]) demonstrates pain improvement for bone pressure was only significant in the control group rather than the experimental group with a mean difference of 1.1 out of 10, 95% CI 0.0-2.3, ($p= 0.05$); with no significance shown for muscle pressure or running. Study by Gomez et al. (*Int J Surg*. 2017;46:102-109. doi: S1743-9191(17)31244-X [pii]) showed clinical and statistical significance with an NNT value of 2, ($p= 0.001$), and mean change from baseline of 4.61. Finally, study by Rompe et al. (*Am J Sports Med*. 2010;38(1):125-132. https://doi.org/10.1177/0363546509343804. doi: 10.1177/0363546509343804) showed pain improvement was statistically significant with ($p <.001$) and mean change from baseline of 5.4.

Conclusions: Evidence supporting the use of extracorporeal shock wave therapy for pain improvement in adults with MTSS was conflicting between the three articles studied in this systematic review. Two studies found this treatment statistically significant while one did not display any significance with shockwave therapy.

Key Words: Shockwave, medial tibial stress syndrome

INTRODUCTION

Medial tibial stress syndrome (MTSS), commonly known as shin splints, is an overuse injury that causes pain over the distal portion of the posteromedial tibia spreading over an area greater than 5cm. The pathophysiology of this condition is unclear, but it is believed to be due to microdamage in the cortical bone that is associated with periostitis overlying the distal tibia due to continuous muscle traction.[1,2] The repetitive stress that the bone, connective tissue, and surrounding muscles undergo during high impact exercises causes significant and debilitating pain to the anterior portion of the shin.[1,2]

MTSS is due to high impact exercises such as running and jumping and therefore, is popular in many athletes and military recruits due to the constant strenuous activities they perform on a daily basis. Currently, MTSS affects between 13.6% to 20% of runners and up to 35% of military recruits with a prevalence of 9.5%.[1,2] Additionally, Rompe et al. reports that MTSS contributes to 50% of all lower leg injuries.[3] Of the 50%, 6% to 16% resulted from running.[3] On the other hand, MTSS is not limited to this population alone. Adults diagnosed with prevalent conditions such as diabetes, CVD, and obesity who are encouraged to increase their physical activity for health benefits can be at risk as well.[4,5] Any form of increased physical activity such as an increase in duration, frequency, and intensity can contribute to MTSS.[4,5]

Diagnosis is made clinically with signs and symptoms of dull pain and tenderness to palpation of the distal tibia that is typically worse at the beginning and end of exercising.[1,2] Pain is usually absent during exercise unless it is very severe.[1,2] Since diagnosis for this condition is made clinically, healthcare visits are often required for diagnosis. The exact estimate for healthcare visits each year could not be identified. However, a systematic review by Yeung states, "12% to 44% of patients with lower leg soft tissue injuries require medical attention".[6] This percentage of medical attention for MTSS also leads to significant healthcare cost. Yeung's review also states, lower leg soft tissue running injuries have a huge effect on morbidity and healthcare cost.[6] It is important to properly diagnose and obtain professional healthcare for this condition. If left untreated it can progress to a stress fracture which will cause a tremendous elevation in medical attention, testing, and healthcare cost, leading to greater debilitation that could have been prevented.

The mainstay of treatment for MTSS is activity modification with relative rest. Other conservative treatment methods such as ice, NSAIDS, stretching and strengthening, attention to biochemical factors, orthotics, and kinesiotaping have been shown to be somewhat effective in the treatment of MTSS.[2,3,7] The problem with these forms of treatment is that it is all require moderate time before effects are realized. Presently, there is not an intervention that quickens the process of recovery or decreases treatment time. Other techniques attempted are cryotherapy, laser therapy, acupuncture, ultrasound, and corticosteroid injections.[2,3,7] In severe refractory cases, surgery with a fasciotomy of the posterior superficial compartment of the leg can be considered.[2,3,7] Currently, there is unclear evidence for the best management for MTSS with low quality evidence that many of the above treatments are effective. Prevention and treatment of this condition should be explored in further detail. Therefore, shockwave therapy should be studied as an alternative form of treatment to effectively improve pain caused by medial tibial stress syndrome. This systematic review will evaluate two randomized controlled trials and a cohort study comparing the efficacy of extracorporeal shock wave therapy for improving pain in adults with medial tibial stress syndrome.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not extracorporeal shock wave therapy is an effective treatment for improving pain in adults with MTSS.

METHOD

Two randomized controlled trials and a cohort study that consisted of adults with medial tibial stress syndrome were selected for this review. The interventions used in these studies was extracorporeal shock wave therapy and its comparisons were sham dose shockwave therapy, an exercise program, and a home training program. Newman et al. used a standard dose shockwave therapy that progressively increase each week from 0.1 to 0.3 mJ/mm^2 at 1500 pulses while the control group received a sham dose of shockwave therapy, the lowest dose deliverable at 0.01 mJ/mm^2 at 1000 pulses in week 1 and 1500 pulses thereafter.[8] Gomez et al. used a single session of 1500 pulses of 0.20 mJ/mm^2 and frequency of 5 Hz combined with an exercise program of 40 minutes of exercise 5 days a week, control group only used the exercise program.[7] Rompe et al. used an intervention of 3 low-energy treatments in weekly intervals of 2000 shocks with 0.1mJ/mm^2 combined with a home training program while the control group only used the home training program.[3] Outcomes measured were numerical rating scale and visual analog scale.

The studies were found in peer reviewed journals though PubMed and Google Scholar. The keywords used for this search were “shockwave” and “medial tibial stress syndrome”. Articles were selected based on if their material qualified to answer the clinical question being discussed and if the outcomes were relevant to or oriented to the patient (POEMS). These articles were published from 2010-2017. Inclusion criteria includes studies published after 2007, with male and female participants who were 18 years old or older who were experiencing pain to the posteromedial tibia with exercise. Exclusion criteria includes studies published in 2007 or earlier. The statistics reported in these studies were mean change from baseline, standard deviation, NNT, EER, CER, RBI, ABI, CI and p-values.

Table 1. Demographics and Characteristics of Included Studies [3,7,8]

Study	Type	# Pts	Age (yrs)	Inclusion criteria	Exclusion criteria	W / D	Interventions
Newman (2016)	RCT	28	34 ± 11 years	Pain for a minimum of 21 days, involving distal half of posteromedial tibia and spread 5cm or more with running based activity, pain lasted hours or days after exercise, no paresthesia's	Shockwave therapy used prior for treatment, another concurrent diagnosis or lower limb injury (compartment syndrome, stress fracture, joint sprain)	4	Standard dose shockwave therapy that progressively increased each week. Dose progressed from 0.1 to 0.3mJ/mm^2 at 1500 pulses.
Gomez (2017)	RCT	42	>18 years old	>18 years old with pain during exercise and after on the posterior medial part of the tibia. Pain on palpation that spreads 5cm, minimum of 3 weeks of pain, unilateral pain, no stress fracture	Patients with stress fracture or other types of fractures, osteomyelitis, tumor, infection, compartment syndrome, prior surgery shockwave therapy, coagulation disorder, pregnancy, rheumatic disease	0	Single session of 1500 pulses of .20mJ/mm^2 and frequency of 5 Hz combined with an exercise program of 40 minutes of exercise 5 days a week
Rompe (2010)	Cohort Study	47	Mean age 41 years (18-56)	Unilateral chronic MTSS for 6 months before treatment and failed 3 forms of nonoperative measures for 3 months	Osteomyelitis, osteoarthritis, fractures, tumors, compartment syndrome, rheumatoid arthritis, polyarthritis, <18 years, pregnancy, surgery, infection, bleeding disorder	5	3 low-energy treatments in weekly intervals of 2000 shocks with .1mJ/mm2

OUTCOMES MEASURED

The patient-oriented outcome measured in these trials was pain improvement. This outcome was measured using the numerical rating scale (NRS) and visual analog scale (VAS). Newman et al. used the numerical rating scale which ranges from 0-10, with 10 being the worst pain imaginable and 0 being no pain at all.[8] Pain was measured during bone and muscle pressure (5 kg of pressure applied) as well as during running (until pain level reached 4 out of 10).[8] The results were compared from the control group and experimental group from week 1 to week 10.[8] Rompe et al. also used the numerical rating scale to assess pain which was collected at baseline, 1 month, 4 months, and 15 months.[3] Gomez et al. used the visual analog scale (VAS), which recorded pain level on a scale from 0-10 during rest and at the end of running.[7] Pain greater than or equal to 4 was considered moderate to high pain levels. These scores were recorded and compared over 4 weeks between the experimental group and the comparison. Mean change from baseline and p values were recorded to determine the effectiveness of the treatment groups compared to the control groups.

RESULTS

The double-blind randomized control trial by Newman et al. conducted a study on 28 participants, 18 females and 10 males with a mean age of 34 years old.[8] Of the 28 participants 4 were lost to follow up.[8] Participants were included in the study after being diagnosed with MTSS by clinical examination and consultation with a sports physiotherapist.[8] Participants were randomly allocated into an experimental group and a control group with similar demographics at baseline. Allocation was concealed from the recruiter and participants. The experimental group received a standard dose shockwave therapy that progressed from 0.1 to 0.3 mJ/mm^2 at 1000-1500 pulses from week 1 to week 10 with a cumulative dose of 1450 mJ/mm2 divided in 5 sessions.[8] The control group received the lowest shockwave dose possible of 0.01 mJ/mm^2 at a 1000-1500 pulses, with a cumulative dose of $70mJ/mm^2$ over 5 sessions.[8]

The outcome of the study was to assess pain improvement with bone pressure, muscle pressure, and running at the end of the 10 weeks between the experimental group and the control group.[8] This outcome was measured using the numerical rating scale and reported as mean change from baseline, standard deviation, and 95% CI. The mean change from baseline was only significant for bone pain which was 1.9 for the control and 0.6 for the experimental group.[8] This illustrates bone pain improvement was greater in those receiving the sham dose shockwave therapy (control group) and was calculated to be statistically significant with a mean difference of 1.1 out of 10, 95% CI 0.0-2.3, and p value of 0.05.[8] For muscle pain during running the mean change from baseline, standard deviation, and 95% CI was not significant when comparing the experimental group to the control group and is demonstrated in Table 2.[8]

Table 2. Comparison of Intervention group and Control group at baseline and week 10 [8]

Outcome	**Groups**				**Difference between groups**
	Week 1		**Week 10**		**Week 10 minus week 1**
Pain NRS (0-10)	**Exp (N=14)**	**Con (n=14)**	**Exp (n=12)**	**Con (n=12)**	**Exp min Con**
Bone pressure	5.9 (2.4)	5.5 (2.0)	5.3 (2.4)	3.6(1.7)	1.1 (0.00 to 2.3)
Muscle pressure	3.6 (2.5)	3.9 (1.8)	3.3 (1.6)	3.2 (1.8)	0.2 (-1.5 to 1.9)
Running	6.9 (1.3)	6.6 (2.0)	3.2 (2.5)	2.9 (3.0)	-0.1 (2.9 to -2.7)

Mean (SD) of groups and mean (95% CI) difference between groups

Gomez et al. conducted a single-blind randomized controlled study consisting of 42 military cadets, 33 men and 9 women, at the Military School of Cadets of the Colombian Army.[7] These participants were diagnosed with MTSS and enrolled by the orthopedic surgeon who was blinded to the patient's treatment allocation. The cadets were randomly assigned to the experimental group who received a single session of 1500 pulses at 0.20 mJ/mm^2 at 5 Hz frequency along with a specific exercise program or the control group who just received the exercise program which consisted of 40 minutes of exercise, five days a week for 4 weeks with a physiotherapist.[7] Allocation was concealed from the recruiter and the participants. The control group also received cryotherapy after performing the exercises in attempt to mitigate the biological effects of ESWT.[7]

The endpoint of the study was to assess if pain improvement at the end of running was greater in the experimental group versus the control group. Gomez et al. was able to dichotomize their data by using the visual analog scale for pain.[7] Participants were classified as either having a high level of pain (VAS≥4) versus a low level of pain (VAS<4) at baseline and at the end of treatment which is displayed in Table 3.[7] From the data in Table 3, NNT, EER, CER, RBI, and ABI were able to be calculated and are displayed in Table 4. The results confirmed to be clinically significant with an NNT value of 2.[7] In addition, the experimental group showed statistical significance over the control group with p=0.001 and a mean change from baseline of 4.61 compared to 3.05 for the control group.[7]

Table 3. Comparison of Experimental and Control groups at baseline and 4 weeks.[7]
Percent reduction of pain for both groups using VAS[7]

Group & Variables	Before treatment		At the end of treatment	
	Frequency	Percentage	Frequency	Percentage
	ESWT + Exercise			
VAS (end of running)				
High pain	23	100.0	7	30.4
Low pain	0	0.0	16	69.6
	Exercise			
High pain	19	100.0	17	89.5
Low pain	0	0.0	2	10.5

Table 4. Comparison of Experimental and Control groups in Gomez et al.

CER	EER	RBI	ABI	NNT
0.11	0.70	0.84	0.59	2

The cohort study conducted by Rompe et al. consisted of 94 subjects, 54 women and 40 men, diagnosed with MTSS; who were divided into an experimental group and a control group with 10% being lost to follow up.[3] There was no significant difference in sex, age, and symptom duration between the experimental group and the control group at baseline. Each group was treated with rest, ice, and rehabilitation exercises (calf stretching, Thera-Band strengthening, heel raises, toe raises) twice a day for 12 weeks.[3] The experimental group was also given 3 shockwave treatments of 2000 shocks at 0.1 mJ/mm^2 at 2, 3, and 4 weeks.[3]

The outcome of the study was to determine if pain improvement was significantly better for the experimental group compared to the control group using the numerical rating scale. Mean NRS score improved in the experimental group from 8.1 at baseline to 2.7 at the end of 15 months, demonstrating a mean change from baseline of 5.4.[3] The control group only demonstrated a mean change of 3.3 at the end of the 15 months.[3] Furthermore, the between group difference for 1 month, 4 months, and 15 months was statistically significant with $p<.001$.[3]

Table 5. Comparison of Experimental and Control groups at baseline, 1, 4, and 15 months[3]
Mean NRS score and (mean change from baseline)[3]

	Pretreatment	**1 month**	**4 months**	**15 months**
Experimental	8.1 + 3.4	5.8+0.9 (2.3)	3.8+1.1 (4.3)	2.7+0.9 (5.4)
Control	8.5+3.1	7.3+2.9 (1.2)	6.9+0.8 (1.6)	5.3+2.6 (3.2)
Between-group difference (p-value)		P<.001	P<.001	P<.001

DISCUSSION

This systematic review evaluated two randomized control trials and a cohort study to illustrate the effectiveness of shockwave therapy for treating pain related to MTSS. Two of the three studies did show statistical improvement in pain with shockwave therapy. However, in the double-blind randomized control trial by Newman et al. pain improvement for bone pressure was only significant in the control group (sham shockwave therapy) rather than the experimental group, with no significance shown for muscle pressure or running. Some explanations to this can be that the trial was only 10 weeks long and symptom duration for MTSS tends to be much longer, with most participants having experienced pain for an average of 30 months.[8] Also, the participants in this study did not decrease their activity levels which is an important intervention used in treating MTSS.[8] Another limitation is that the shockwave probe was directed towards the bone rather than the musculature which can be why pain improvement with bone was the only significant measure.[8] Furthermore, the dose of shockwave therapy may be more beneficial at low doses which is why the sham dose may have shown improvement over the experimental group.[8] The main limitation to this trial is the small sample size of only 28 participants, this study is therefore not generalizable to patients with medial tibial stress syndrome and a larger sample size should assessed.[8]

In the study conducted by Gomez et al. pain improvement with shockwave therapy showed to be clinically significant with NNT of 2 and statistically significant with a p value of 0.001.[7] One factor to consider in this study is the patients only received one dose of shockwave therapy where other studies obtained multiple. This suggests that shockwave therapy can be more beneficial at small doses or with just one dose. Some limitations to this study are the small sample size of 42 participants that focuses solely on Colombian military cadets and a short follow up of only 4 weeks.[7] Another limitation is that cryotherapy was given to the control group as an alternative form of treatment that was not given to the experimental group.[7]

The cohort study by Rompe et al. demonstrated pain improvement with shockwave therapy that was statistically significant with $p<.001$.[3] Being that this was a cohort study, randomization was not in effect because the subjects chose their group. Also, a placebo arm was not utilized.[3] This study also used a daily at home training program which could raise suspicion to patient compliance.[3] Another limitation to the study is that a prescription of pain medication was allowed at the 4th month follow up if needed.[3]

With each study having its own limitations, one that is present throughout is pain tolerance. In each of these studies pain is self-reported, and all patients experience different levels of pain tolerance which could skew the data.

CONCLUSION

The two randomized control trials and one cohort study discussed in this systematic review showed conflicting evidence on whether or not extracorporeal shock wave therapy is an effective treatment for improving pain in adults with medial tibial stress syndrome. Two studies found this treatment statistically significant while one did not display any significant improvement with shockwave therapy. Further studies should consider testing for the best therapeutic treatment dose and frequency of administering shockwave therapy for pain improvement. They should also consider obtaining a larger sample size and a longer follow up period. Continuing studies on the use of shockwave therapy for pain improvement in adults with MTSS could revolutionize the treatment for MTSS.

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