

The Immediate Effect of Extracorporeal Shockwave Therapy for Chronic Medial Tibial Stress Syndrome

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Abstract

Medial Tibial Stress Syndrome can be a recalcitrant overuse injury in the military.

Objectives: *To report the immediate effect and clinical experiences of extracorporeal shockwave therapy as part of a comprehensive treatment program for patients with chronic Medial Tibial Stress Syndrome.*

Design: *Historic cohort.*

Methods: *Patients received an individualized treatment program, including radial shockwave therapy for 16 weeks. The length of tenderness along the posterior medial tibial border was measured in centimeters during the weeks of shockwave therapy. Pain during and after shockwave therapy was recorded. Patients were asked if they would recommend shockwave therapy.*

Results: *37 male cases were included, median age 23 (IQR 8) years. On average, shockwave therapy did not reduce the length of tenderness during the weeks of application. All patients (100%) reported shockwave to be painful (≥ 6 out of 10), but tolerable by self-application. After the initial shockwave session 25/37 patients (68%) reported no post treatment hours of pain, after session four 33/37 patients (89%). Thirty patients (81%) would recommend shockwave therapy.*

Conclusion: *Radial extracorporeal shockwave therapy did not reduce the length of tenderness along the posterior medial tibial border during the weeks of application in patients with chronic Medial Tibial Stress Syndrome. It is a painful treatment, but tolerable by self-application. The majority of patients did not experience post treatment pain. In this group of patients 81% would recommend shockwave therapy. More studies are necessary to establish if extracorporeal shockwave therapy for Medial Tibial Stress Syndrome is clinically effective.*

Keywords: *Exercise Related Leg Pain, Chronic Exertional Compartment Syndrome, Military, Occupational.*

INTRODUCTION

Medial tibial Stress Syndrome (MTSS) is a common overuse injury in the military [1]. MTSS is a condition involving the interface of the tibial bone and soft tissue [2]. MTSS causes pain along the medial tibial border during and after leg loading activities [3]. Incidence of MTSS varies between 4% and 35% in athletic and military populations [3]. The exact incidence and prevalence of MTSS in the Royal Netherlands Armed

Forces are not known. Information from remedial platoons reveals that exercise related leg pain, including MTSS and Chronic Exertional Compartment Syndrome (CECS), are among the top three overuse injuries leading to drop out from basic and secondary military training [4].

Several treatments for MTSS have been described in the literature, including: reduction of running and jumping, icing, massage, stretching and strengthening

exercises, attention to biomechanical factors such as over-pronation, ultrasound therapy, sports compression stockings, lower leg braces, pulsed electromagnetic fields, and extracorporeal shockwave therapy (ESWT) [5,6]. The optimal management of MTSS remains unclear.

The department of military sports medicine of the Royal Netherlands Army is a secondary care setting. Service members are referred if conservative care on base for at least three months has not produced satisfactory results. Around 100 new patients with exercise related leg pain, including those with MTSS, CECS, or a combination of MTSS+CECS, receive an individualized treatment program each year. The department has an ongoing research assignment to improve the care for service members with overuse injuries from sports and military training. In response to two studies reporting promising results of Extracorporeal Shockwave Therapy (ESWT) for MTSS, this therapy was introduced in our department as part of the chronic MTSS treatment program in 2011 [7,8]. ESWT is a non-invasive treatment in which short burst high intensity sound waves are delivered to targeted tissues to trigger a repair response [9]. Based on their propagation pattern, shockwaves can be focused or unfocused. Studies on bone models reported that ESWT promotes vascularity, enhances osteoblast differentiation and increases chemical mediators of the bone healing process [10]. Assuming that ESWT would support bone healing it was placed in the first weeks of our comprehensive treatment program for service members with chronic MTSS, before initiation of gait retraining.

It is important to investigate the effectiveness of new treatments in our specific patient population. If ESWT is an effective intervention in patients with MTSS, a change in length of the tender medial tibial portion might be an indication of its effectiveness. Previous studies noted that ESWT to the medial tibial border can be painful [8]. The feasibility of a treatment may depend on acceptable levels of pain during and after application. This makes monitoring adverse reactions and patient satisfaction with ESWT important. Therefore, the aims of this observational study were to: 1. determine the effectiveness of ESWT on the bone healing process during the weeks of ESWT application; 2. to monitor pain during and after ESWT and record patient satisfaction with ESWT.

METHODS

This historic cohort was performed in the Department of Military Sports Medicine of the Royal Netherlands Army, Utrecht, The Netherlands. This is a secondary care institute. According to the declaration of Helsinki approval of an ethical board for this type of study was not required. All patients gave permission in writing for aggregate, anonymous use of their treatment data.

Inclusion

Service members from all armed forces and all types of military specialties, who were referred to our department for the first time in 2013, were eligible for inclusion. Inclusion criteria were: male sex, diagnosis chronic MTSS, or a combination of MTSS with another overuse injury of the leg. Exclusion criteria were: the patient did not complete the program due to military tasks, the patient had psychological problems or any other affliction that could impede with the treatment program. Chronic was defined as complaints lasting more than six months despite treatment in primary care on base. Patients' diagnosis of MTSS was based on history, physical examination and a standardized running test to provoke symptoms. Diagnostic procedures of other overuse injuries of the leg e.g. chronic exertional compartment syndrome, with intra compartmental pressure measurement, were described in detail previously [4]. All patients were initially seen by a single, experienced sports medicine physician (WZ), using a detailed intake, diagnostic and treatment protocol for exercise related leg pain.

During intake, the following baseline parameters were collected: duration of symptoms (months), repeat episode of MTSS (yes/no), age (years), biometrics (height in meters, weight in kilograms), and diagnosis. The single assessment numerical evaluation (SANE intake) was recorded. This SANE score is a single question instrument evaluating patients' subjective injury status with the following question: "how would you rate your lower leg today as a percentage of normal, on a 0-100 scale, with 100 being normal". The SANE score was developed and validated in a military health care setting [11].

INDIVIDUALIZED CONSERVATIVE OUTPATIENT TREATMENT PROGRAM

Depending on observed risk factors, the following previously-proven helpful components were selected (along with shockwave treatment) to create a custom

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rehabilitation program for servicemembers [5,6]: stretching and/or strengthening of lower extremity musculature, massage of hypertonic musculature, dry needling of trigger points, prescription of compression stockings, evaluation of running shoes, evaluation / prescription of shoe inlays, maintaining fitness with a low impact training program, gait retraining of running and a progressive running schedule. Massage was performed by a physical therapist; all other modalities were self-administered or administered by the sports physician. For each of the aforementioned interventions local protocol described criteria for application (appendix, detailed exercise related leg pain treatment protocol 2013). Every service member received a 6-week progressive running program building up to a 15-minute uninterrupted run free of pain in rest. Some service members with a physically demanding specialty, received an additional 6-week progressive running schedule to build to a 30-minute uninterrupted run, beyond the 16-week evaluation point.

EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT)

ESWT was always the first intervention of the comprehensive treatment program. Patients were instructed to refrain from load bearing exercise, such as running and jumping, during the weeks of ESWT. Patients received four consecutive radial ESWT sessions at one week intervals. If patients were not

able to attend four weeks consecutively, they received five sessions over a period of six weeks. Shockwave treatment was performed by self-application, in a sitting position, after initial instruction by the attending physician (Figure 1). At every session, 2000 unfocused (or “radial”) shocks were administered per leg, with a frequency of eight shocks per second and intensity set at 2,5 bar (Swiss DolorClast, Nyon, Swiss), copying the machine settings used by Rompe [8]. Local anesthesia was not applied, also conforming to Rompe’s protocol [8]. To determine the effectiveness of ESWT, the change in length of the tender area of the medial tibial region was calculated. For this, first patients were instructed to palpate the medial tibial border before each ESWT session and accurately indicate the tender area with a skin marker. Patients were unaware of the primary research objective to minimize the chance of outcome manipulation. Next, the length of the marked tender area was measured in centimeters, rounded to an integer, by the first author (WZ). This procedure was repeated before each next ESWT session.

During each ESWT session patients were asked if the treatment was painful, expressed as 6 or more on a 0-10 Numerical Rating Scale (yes/no). In addition, from the second session of ESWT onward, all patients were asked to report any adverse effects of the previous ESWT session, in particular post treatment pain, reported as the number of hours of post treatment leg discomfort in five categories.



Fig 1. Shockwave treatment was performed by self-application, in a sitting position, after initial instruction by the attending physician.

SUBJECTIVE FINAL EVALUATIONS

During final evaluation, approximately four months after intake, patients were asked if they would recommend ESWT for MTSS (yes/no).

STATISTICS

Baseline age, biometrics, and characteristics of the complaints: i.e. duration of symptoms, repeat episode of MTSS, diagnosis and the SANE score at intake were described with appropriate measures of central tendency and dispersion. Normality of the data was checked visually by means of histograms, boxplots, and QQ-plots. The length of the tenderness measured before each ESWT session was presented in a table, per patient group (four or five ESWT sessions). To determine the effectiveness of ESWT on the bone healing process, the differences in length between first and final ESWT session were tested for statistical significance by means of a paired sample t-test or the Wilcoxon signed-rank test if the parametric assumptions were not met. Pain during (yes/no) and post ESWT (1= no pain; 2 = < 12 hrs; 3 = 12-24 hrs; 4 = 24-48 hrs; 5 = > 48 hrs) was described.

Patient recommendation of ESWT (yes/no) were described. All tests were performed using SPSS version 24.0. The level of significance was set at $p < 0.05$.

RESULTS

In total 37 male cases in the year 2013 met all the criteria for inclusion. Table 1 shows relevant baseline characteristics of the service members in this study.

ESWT

Table 2 shows the length of the tender posterior medial tibial area identified by the patients before all ESWT sessions. 28/37 patients (76%) received four ESWT sessions, 9/37 patients (24%) received five ESWT sessions. There was no significant change in the average length of the posterior medial tibial tender area identified by the patients from the first (27.9 cm, ± 10.4) to the last ESWT session (4-ESWT group: 27.1 cm, ± 11.0 cm), (5-ESWT group: 30.2 cm, ± 14.5 cm), $p < .05$.

All patients (100%) reported ESWT to be a painful treatment (numerical rating scale ≥ 6 out of 10), during all sessions. After ESWT session one, 25/37 patients (68%) reported no post treatment hours of pain/discomfort, after ESWT session four 33/37 patients (89%) reported no post treatment pain.

SUBJECTIVE FINAL EVALUATIONS

Thirty patients (81%) would recommend ESWT for MTSS treatment.

Table 1. Baseline characteristics of 37 cases in this study.

	All Cases (n = 37)
Mean age (years) \pm SD	24.6 \pm 5.6
Mean height (m) \pm SD	1.81 \pm 0.06
Mean weight (kg) \pm SD	82.3 \pm 8.7
Mean BMI	25.2 \pm 2.4
Median Duration of symptoms (months) / IQR	7 / 8
Repeat episode of MTSS (yes/no)	24 (65%)
Diagnosis: MTSS	16 (43%)
Diagnosis: MTSS + CECS (ICPM > 35 mmHg)	15 (41%)
Diagnosis: MTSS + other ERLP	6 (16%)
Mean SANE intake \pm SD	56.3 \pm 18.2

SD = standard deviation

BMI = body mass index

IQR = inter quartile range

MTSS = medial tibial stress syndrome

CECS = chronic exertional compartment syndrome

ICPM = intra-compartmental pressure measurement

ERLP = exercise related leg pain

SANE = single assessment numerical evaluation.

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Table 2. Length of the area of tenderness on the posterior medial tibia on both legs, identified by patients, per ESWT session. Column 7 and 9 compare the length of the tender area with the initial situation, expressed as a percentage, in order of increasing values. Note: reduction of tenderness and increase of tenderness, both in approximately half of all patients, leads on average to insignificant change.

case number	ESWT protocol	ESWT session 1 length of tenderness on 2 legs cm	ESWT session 2 length of tenderness on 2 legs cm	ESWT session 3 length of tenderness on 2 legs cm	ESWT session 4 length of tenderness on 2 legs cm	length of tenderness 2 legs percentage of session 1	ESWT session 5 length of tenderness on 2 legs cm	length of tenderness 2 legs percentage of session 1
1	4 in 4	22	21	15	12	54.5		
2	4 in 4	36	36	30	24	66.7		
3	4 in 4	15	17	14	10	66.7		
4	4 in 4	15	15	12	10	66.7		
5	4 in 4	31	27	27	22	71.0		
6	4 in 4	54	44	42	40	74.9		
7	4 in 4	26	20	21	20	76.9		
8	4 in 4	20	15	18	16	80.0		
9	4 in 4	40	43	37	33	82.5		
10	4 in 4	29	29	26	24	82.8		
11	4 in 4	24	24	23	22	91.7		
12	4 in 4	23	22	18	22	95.7		
13	4 in 4	30	32	30	29	96.7		
14	4 in 4	44	44	44	44	100.0		
15	4 in 4	30	26	30	30	100.0		
16	4 in 4	32	38	34	33	103.1		
17	4 in 4	15	18	13	16	106.7		
18	4 in 4	42	42	45	45	107.1		
19	4 in 4	9	11	12	10	111.1		
20	4 in 4	22	29	26	25	113.6		
21	4 in 4	20	22	22	23	115.0		
22	4 in 4	31	35	33	37	119.4		
23	4 in 4	20	23	19	24	120.0		
24	4 in 4	40	45	46	48	120.0		
25	4 in 4	25	35	35	32	128.0		
26	4 in 4	32	38	43	42	131.3		
27	4 in 4	24	33	38	37	154.2		
28	4 in 4	16	22	22	30	187.5		
29	5 in 6	17	14	14	14		8	47.1
30	5 in 6	17	17	14	13		13	76.5
31	5 in 6	24	23	22	24		24	100.0
32	5 in 6	50	50	50	50		50	100.0
33	5 in 6	31	31	28	31		31	100.0
34	5 in 6	27	34	34	31		30	111.1
35	5 in 6	39	46	44	42		44	112.8
36	5 in 6	39	45	50	50		46	117.9
37	5 in 6	21	19	26	24		26	123.8
average		27.9	29.3	28.6	28.1	100.9	30.2	98.8
stdev		10.4	10.9	11.6	11.0	29.0	14.5	23.7

4 in 4 = 4x ESWT in 4 weeks, 5 in 6 = 5x ESWT in 6 weeks, ESWT = extracorporeal shockwave therapy, Stdev = standard deviation.

DISCUSSION

This study evaluated the effect of radial ESWT on the length of the tender area on the posterior medial tibial border in a military population with chronic MTSS. The most important findings were that radial shockwave did not reduce the length of the tenderness during the weeks of application. Despite it being a painful treatment, 81% in this group of patients would recommend ESWT.

The premise of this study was that ESWT would trigger a repair response in bone and reduce the length of the tender area on the posterior medial border during the weeks of application. This did happen in about half of patients, but not in the others, neutralizing an average effect (Table 2). Possibly the positive effects of ESWT on bone in this patient group are delayed into the weeks of running resumption; possibly the effect of ESWT is to reduce the intensity of pain on the medial tibial area first, before the palpable length of the tender area is reduced. This study clearly indicates that the clinical effectiveness of ESWT for MTSS for our specific patient group needs to be established in a randomized trial, such as previously performed in athletes by Moen [7].

Rompe et al. reported that radial ESWT to the medial tibial border was painful in eight of 47 patients [8]. Our experience was very different. Using the same radial ESWT machine, with the exact same settings (number of shocks, frequency and pressure), all of our patients (100%) reported the treatment to be painful, defined as six or more on a 0-10 scale. In fact, in the preparation phase for this study it was discovered that patients strongly preferred self-application, and this has become the standard way of providing ESWT to the tibia in our department. Self-application offers the patient the opportunity to give more shocks to the most sensitive areas and to interrupt the treatment briefly if pain becomes excessive.

Gomez Garcia is the only other study to report on ESWT for MTSS in a military population [12]. However, the circumstances of the current study and the Gomez Garcia study were quite different. Gomez Garcia gave a single session of focused ESWT to military cadets with a minimum of three weeks of symptoms. All patients returned to activity and running four weeks after treatment [12]. In our study, patients had symptoms on average more than 12 months, received four or five sessions of radial ESWT and not all returned to pain

free running. In our study return to active duty was not tracked. Return to active duty, particularly to the same military specialty, is a useful outcome measure in the military. We intend to track this in the future.

This study was not designed to investigate the optimal number of ESWT sessions. However, the extra ESWT session did not yield an additional treatment effect. Given the small number of patients receiving an extra ESWT session, this comparison has low power and should be interpreted with caution. In future studies on ESWT for MTSS, the optimal number of ESWT sessions, the optimal pressure and the optimal distribution of sessions over days or weeks should be further investigated [9].

This study suffers from the inherent limitations of an analysis of regular care. A heterogeneous group of patients received individualized treatments plans and two different ESWT protocols were used. There was no control group. The study method, measuring the length of the tender medial tibial area with a ruler, has not been described before and has not been validated. Acknowledging these major limitations, we conclude that ESWT did not reduce the length of the tender area on the posterior medial tibial border during the weeks of application and we reveal that self-application of ESWT for MTSS is preferred by patients.

Based upon the positive patient recommendations reported in this study, and positive reports in the literature [7, 8, 13], ESWT has remained part of our treatment program for service members with chronic MTSS. Since 2013, promising short- and medium-term treatment results for this particular group of patients have been published by our department [14]. The results are attributed to increased attention to gait retraining in both running shoes and military boots. In our view the combination of ESWT and gait retraining was very important in the treatment of chronic MTSS in the military, but the current study shows the need for further evaluation of the ESWT component of the comprehensive treatment program.

This study also illustrates the impact of MTSS on service members and the military organization. In our patient group 65% suffered from a repeat bout of exercise related leg pain. In a time where recruiting and retaining young men and women in the military is very difficult, efforts in primary prevention of MTSS are paramount, with continuing emphasis on developing efficient and durable early-stage treatment strategies to prevent chronic and recurrent symptoms [15].

CONCLUSION

A group of military patients with chronic MTSS received radial ESWT as part of their treatment program. During the weeks of application the length of the tender posterior medial tibial border did not decrease. ESWT to the medial tibial border was a painful treatment, but tolerable when self-applied. The majority of patients did not experience post treatment pain. In this group of patients 81% would recommend radial ESWT.

PERSPECTIVE

MTSS can be a recalcitrant overuse injury in athletes and service members. No treatment for MTSS can be recommended as superior, but ESWT seemed to have promise.^[5,7,8] This study showed that ESWT did not have an immediate effect on tenderness of the medial tibial border in military patients with chronic MTSS. Nevertheless, in this group of patients the majority would recommended ESWT. More studies are necessary to establish whether ESWT for MTSS is clinically effective and to better understand the underlying physiological working mechanisms [9].

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APPENDIX

Standard care for chronic MTSS: criteria for application (version 2013)

intervention	criterion
stretching	Gastrocnemius tightness = minimal angle compared to a vertical line: 70 degrees or more (fig A); Soleus tightness = maximal distance 5 cm from the wall or less (fig B).
strengthening	Calve strength: not able to perform 30 consecutive calve raises on 1 leg
Massage hypertonic m. plantaris	m. plantaris palpation painful
Dryneedling of triggerpoints	Medial and lateral gastrocnemius: if patient identifies the calve as a pain location.
Compression stockings	Not for patients with proven anterior CECS (ICPM \geq 35 mm Hg).
Shockwave ESWT	For MTSS only: once a week, 4 sessions; each session 2000 radial shocks, frequency 8 per second and intensity 2.5 bar, on the medial tibial border.
New running shoes	Every year or 500 miles (800 km); If patient describes a relation between symptoms and shoes; Minimalist shoes are discouraged.
Customized anti-pronation inlays	If navicular drop is positive ($>$ 0.5 cm) and if over-pronation is established with slow motion video analysis of barefoot running
Maintaining fitness with low impact training	Resume three moments of low impact exercise per week. Keep leg pain scores \leq 3 (on a Numeric Pain Rating Scale 0-10).
Gait retraining while running in sports shoes	Change to a ball-of-foot strike (reduce heel strike), when applicable. 10% reduction of stride length; Aim for cadence 180/minute.
Progressive running schedule	Week 1-6: run twice a week, end goal 15 minute uninterrupted run; Week 7-12: run twice or three times per week, end goal 30 minute uninterrupted run.



Appendix, Fig A: Gastrocnemius / Achilles stretch (right leg, barefoot), criterion for normal value = maximal angle compared to a vertical line: 70 degrees or less.



Appendix, Fig B: Soleus stretch (left leg, barefoot), criterion for normal value = minimal distance 5 cm from the wall or more.

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