



Original Research

Shockwave treatment for medial tibial stress syndrome in military cadets: A single-blind randomized controlled trial



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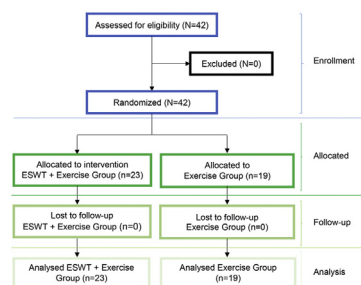
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HIGHLIGHTS

- Medial tibial stress syndrome (MTSS) is characterized by pain in the lower leg, common in athletes and militaries.
- Although MTSS is often mild, it can evolve to chronicity.
- Optimal treatment for MTSS has yet to be established.
- Extracorporeal shockwave treatment (ESWT) is a tool aimed at alleviating symptoms and shortening recovery time in MTSS.
- A single focused ESWT combined with a specific exercise program allows faster recovery in military cadets with MTSS.

GRAPHICAL ABSTRACT



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ABSTRACT

Medial tibial stress syndrome (MTSS) is a common injury in athletes and soldiers. Several studies have demonstrated the effectiveness of extracorporeal shockwave treatment (ESWT) in athletes with MTSS. **Objective:** To assess whether one session of focused ESWT is effective in the treatment of military cadets with MTSS.

Design: A randomized, prospective, controlled, single-blind, parallel-group clinical study. Level of evidence: Ib.

Setting: Military School of Cadets of the Colombian Army.

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Keywords:

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Methods: Forty-two military cadets with unilateral chronic MTSS were randomly assigned to either one session of focused electromagnetic ESWT (1500 pulses at 0.20 mJ/mm²) plus a specific exercise programme (muscle stretching and strengthening exercises) or the exercise programme alone.

The primary endpoint was change in asymptomatic running test (RT) duration at four weeks from baseline. Secondary endpoints were changes in the visual analogue scale (VAS) after running and modified Roles and Maudsley (RM) score also at four weeks from baseline.

Results: ESWT patients were able to run longer. Mean RT after four weeks was 17 min 33 s (SE: 2.36) compared to 4 min 48 s (SE: 1.03) in the exercise-only group ($p = 0.000$). Mean VAS after running was 2.17 (SE: 0.44) in the ESWT group versus 4.26 (SE: 0.36) in the exercise-only group ($p = 0.001$). The ESWT group had a significantly higher RM score, with excellent or good results for 82.6% of patients vs. 36.8% in the exercise-only group ($p = 0.002$). No significant adverse effects of ESWT were observed.

Conclusion: A single application of focused shockwave treatment in combination with a specific exercise programme accelerates clinical and functional recovery in military cadets with MTSS.

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1. Introduction

Medial tibial stress syndrome (MTSS), also known as shin splints or tibial periostitis, is characterized by pain in the middle and lower end of the tibia; the pain is usually elicited by practising sports or other physical activities [1–3]. The criteria for diagnosis of MTSS were established by Yates and White [4]. Although the prognosis of MTSS is usually benign, it can evolve to chronicity and be disabling [5]. It is a common cause of leg pain in military personnel and athletes [6,7], with incidences ranging between 4% and 35% in these populations [8,9]. Basic training can cause tibial periostitis in 4–10% of recruits after 8–12 weeks [9,10]. In fact, 60–80% of cases are associated with musculoskeletal overload [11]. Prolonged military marching and physical activity involving excess training of the lower limbs contribute to the stress reaction of the bone [12–15], as confirmed by imaging studies [13,16–21]. This condition has been considered a precursor stage for stress fracture, which, unlike MTSS, presents more localized pain that is accentuated on percussion [22] and has a different treatment and prognosis.

According to the theory of bone stress reaction introduced by Moen et al. [23], oedema in the bone marrow is a sign of bone remodelling secondary to overload in people subjected to repetitive strain on the lower limbs. This may cause clinical signs and symptoms when the load exceeds a certain threshold, due to microscopic fatigue (microlesions), as explained in the mechanostat model [24].

To date, no in-depth studies have been carried out on specific treatments for MTSS. Several forms of conservative treatment have been applied in the acute phase, such as relative rest [25–29], anti-inflammatory drugs, analgesics and cryotherapy [9], electrotherapy [30], laser [31], acupuncture [32,33], orthotics [34,35], foot orthoses [36], prolotherapy [37], compression [38], corticosteroid injections [39] and kinesiotaping [40], with varying results. Fasciotomy of the posterior superficial compartment of the leg has also been performed [41–47], but no preferred therapeutic approach has been identified yet. The clinical course is generally prolonged despite treatment, with periods of relapse.

A therapeutic alternative is currently being studied aimed at reducing pain and shortening recovery time in MTSS, using extracorporeal shockwave treatment (ESWT). Two studies from Rompe [48] and Moen [49] have shown ESWT to be effective for MTSS, whereas another study from Newman showed no benefit [50].

Furthermore, as literature has pointed the efficacy of 3 ESWT sessions in MTSS, we studied if one ESWT session was effective in this pathology as well.

The aim of this study was to evaluate the effectiveness of ESWT

in a military population with MTSS.

2. Materials and methods

We performed a single-blind randomized controlled study in 42 military cadets (33 men and 9 women) with MTSS from the Military School of Cadets of the Colombian Army, between February and April 2015.

Inclusion criteria were as follows: 1) patients of either sex, aged over 18 years, diagnosed with MTSS per Yates and White criteria [4], with pain during exercise in the posterior medial part of the tibia, and an area of diffuse pain on palpation measuring at least 5 cm; 2) continuous pain that had appeared at least 3 weeks earlier; 3) pain elicited by exercise and occurring during and after exercise; 4) unilateral pain; 5) X-Ray were performed to rule out stress fracture or other types of fracture.

Exclusion criteria were as follows: 1) patients with current or prior radiological signs of stress fractures or other types of fracture; 2) local infection or osteomyelitis; 3) tumour in the region; 4) compartment syndrome; 5) prior surgery on the same leg; 6) prior use of shockwaves for MTSS; 7) prior or current rheumatic disease; 8) coagulation disorders; 9) pregnancy.

When all the inclusion criteria and none of the exclusion criteria were met, MTSS patients were enrolled by the orthopaedic surgeon once informed consent had been obtained. To ensure consistency of data collection at baseline, a specially designed protocol was used that included clinical variables, such as the visual analogue scale (VAS), and functional variables, such as the running test (RT), which consisted of running on a treadmill at a fixed speed (10 km/h). The RT was stopped if the patient indicated that pain was too severe to continue or in case of fatigue. Patient satisfaction with the treatment was recorded using the Roles and Maudsley scale (RM). Clinical assessments were performed at baseline and at a follow-up 4 weeks later by an orthopaedic surgeon blinded to patients' treatment allocation.

Patients were randomly assigned to receive either a focused ESWT plus a specific exercise programme (intervention group) or the exercise programme alone (control group). Random allocation was performed by the physiotherapist using Epidat 4.0. Allocation was concealed from the recruiter and participants. The intervention consisted of a single session of 1500 pulses at an energy flux density (EFD) of 0.20 mJ/mm² and a frequency of 5 Hz generated by an electromagnetic device (Duolith SD1 T-Top; Storz Medical), performed by a physician specialized in rehabilitation and certified in the use of shockwaves. ESWT was applied to the most painful affected region on palpation in the tibia, without anaesthesia, with

Table 1
Exercise programme for medial tibial stress syndrome patients.

Muscle stretching exercises	<ul style="list-style-type: none"> • Calf Stretch With Towel • Standing Calf Stretch • Anterior Compartment Stretch
Muscle strengthening exercises	<ul style="list-style-type: none"> • Strengthening Exercises for the Lower Leg muscles with Thera-band®: • Resisted Dorsiflexion Flexion • Resisted Plantar Flexion • Resisted Inversion • Resisted Eversion • Strengthening Exercises for the Lower Leg: • Heel Raises • Toe Raises: Sitting • Toe Raises: Standing • Strengthening of the stabilizing muscles of the hip and pelvis: • Pelvic bridge • Lateral leg lift extension • Lateral flexion leg lift: Clam exercise
Joint mobility exercises	<ul style="list-style-type: none"> • Active Range of Motion of the Ankle

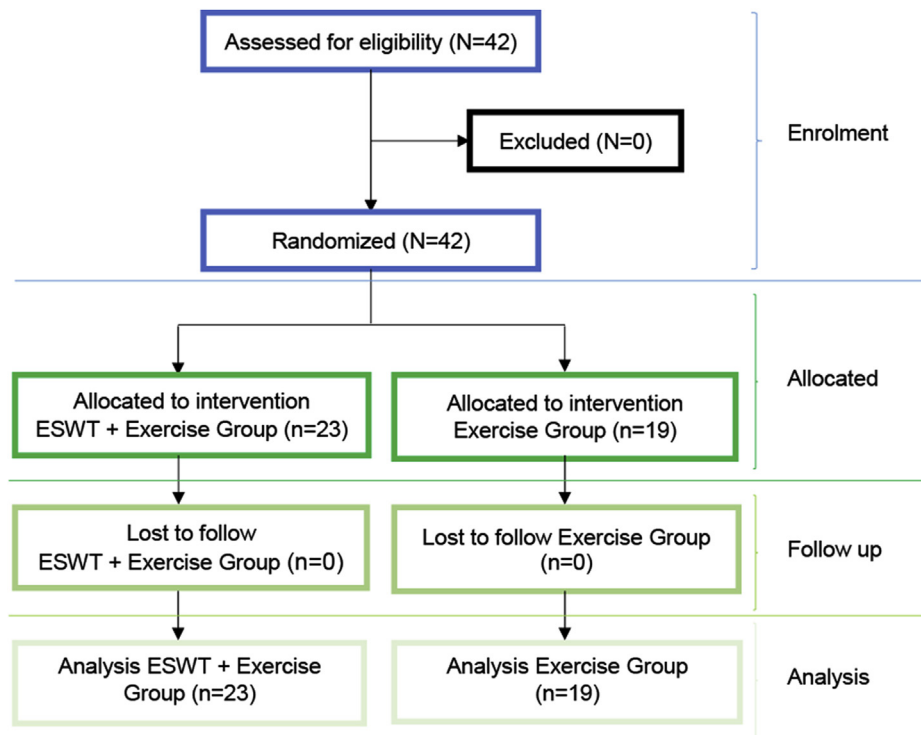


Fig. 1. Consort diagram of participants flow through the trial.

Table 2
Description of the patients in the groups at the start of the study.

Variables	Patient Group				p
	ESWT + exercise (N = 23)		Exercise (N = 19)		
	Mean	SEM	Mean	SEM	
Age	20.04	0.29	19.42	0.35	0.18
Body mass index	24.13	0.56	24.38	0.64	0.78
Number of clinical symptoms at the start	6.96	0.38	7.42	0.30	0.36
Number of overtraining items ^a	15.78	2.02	19.11	2.15	0.27
Gender	N	%	N	%	0.15
Male	20	86.96	13	68.42	
Female	3	13.04	6	31.58	

^a Based on the questionnaire of the French Society for Sports Medicine [53]; SEM, standard error of the mean; N, number of patients.

the patient in the supine position and knee extended. Rest and analgesics were prescribed for 24–48h if necessary. ESWT was combined with an exercise programme (modified from that used by Rompe et al. [48]) consisting of 40 min of exercise five days a week for four weeks under the supervision of a physiotherapist (Table 1).

Patients assigned to the control group received the exercise

programme only. In the control group but not in the ESWT group, cryotherapy was applied to the affected part of the tibia after completion of the exercises during 10 minutes, in order to avoid its possible influence on the biological mechanism of ESWT.

The study design according to the Consort diagram [51] is shown in Fig. 1.

Sample size calculations were based on normal approximation

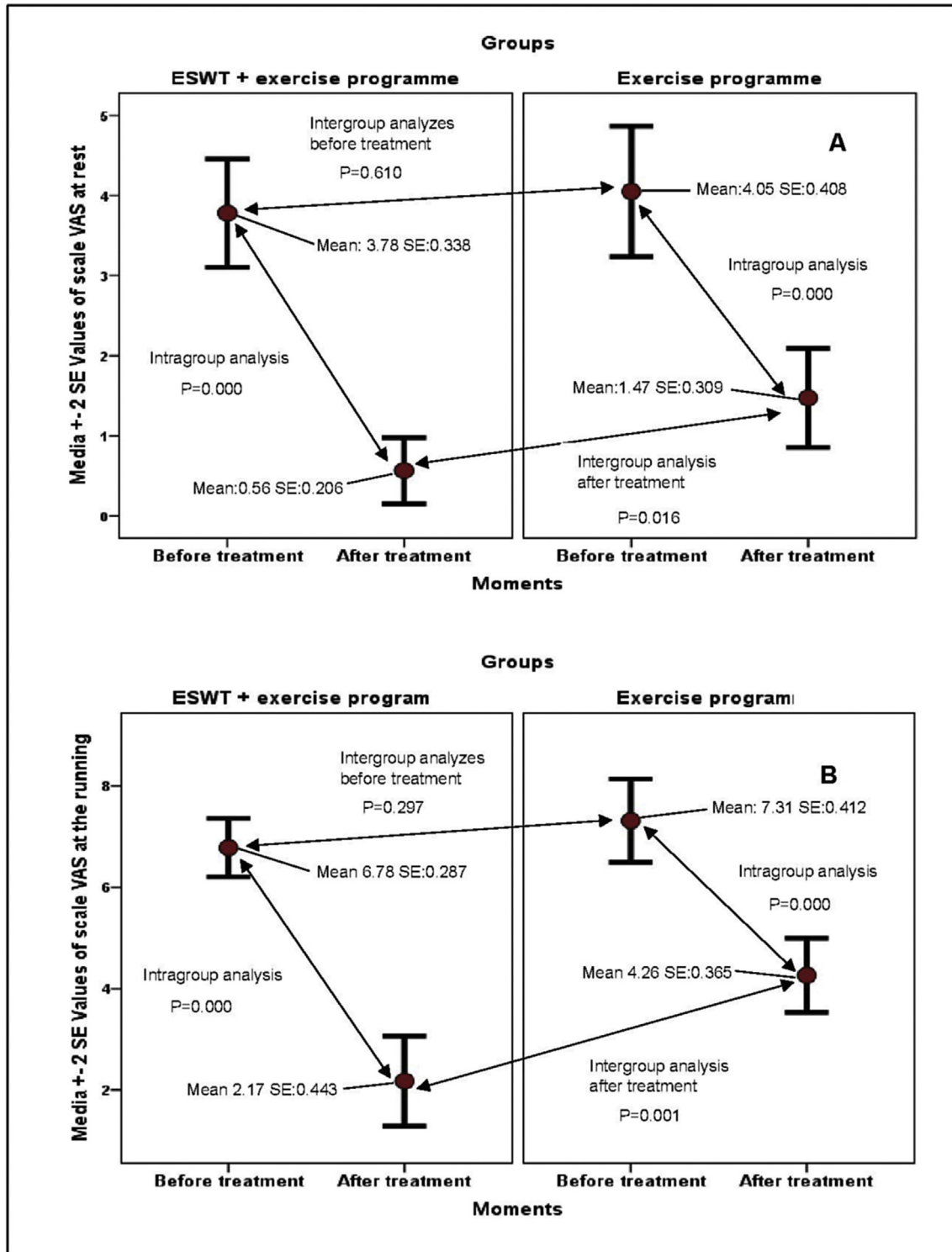


Fig. 2. Pain based on visual analogue scale (VAS) at baseline and follow-up in both groups. Graph A shows VAS at rest; and graph B, VAS at the end of running.

and bilateral contrast with continuity correction. To obtain a sample size ratio of 1:1 for both treatment groups, criteria were $\alpha = 0.05$, $\beta = 0.2$, $P1 = 80.5$ and $P2 = 65$. We obtained a sample size of 46 patients, i.e. 23 in each group. From this sample, 42 patients met the inclusion criteria and none of the exclusion criteria.

Statistical analysis was performed using Windows SPSS version 17.0 software. Student's t-test and Chi-square test were used to compare the two patient groups. Statistical significance was established at $p \leq 0.05$.

The research project was approved by the ethics and research committee of Hospital Militar Central de Colombia (Ref. 7257/DIGE/16/09/2014). The study was carried out in line with the Helsinki Declaration and best clinical practice [52].

Table 3
Percent reduction of pain for both groups.

Group and variables	Before treatment		At the end of treatment	
	Frequency	Percentage	Frequency	Percentage
ESWT + exercise				
VAS at rest				
High level of pain	16	69,6	0	0,0
Low level of pain	7	30,4	23	100,0
VAS at the end of running				
High level of pain	23	100,0	7	30,4
Low level of pain	0	0,0	16	69,6
Exercise				
VAS at rest				
High level of pain	12	63,2	2	10,5
Low level of pain	7	36,8	17	89,5
VAS at the end of running				
High level of pain	19	100,0	17	89,5
Low level of pain	0	0,0	2	10,5

3. Results

The initial statistical analysis showed that both patient groups were homogeneous and therefore comparable (Table 2). There were no dropouts.

The ESWT group showed a significantly greater improvement than the exercise-only group at the end of follow-up, in terms of pain according VAS at rest ($p = 0.016$) and at the end of running ($p = 0.001$) (Fig. 2).

All individuals in the ESWT group who had pain at rest ≥ 4 according to VAS (16 patients), considered as moderate to high pain levels [49], were asymptomatic or improved their pain on follow-up. On the other hand, pain at rest also improved in the control group. In addition, all patients in the control group suffering pain before treatment, improved significantly at follow-up. Furthermore, 69.6% of the intervention group improved pain compared to 10.5% of those treated with exercise alone. (Table 3).

Moreover, patients in the ESWT group were able to run for 17 min 33 s (SE: 2.36) at the end of follow-up, compared to 4 min 48 s (SE: 1.03) in the exercise-only group ($p = 0.000$) (Fig. 3). All patients returned to activity and running in the militar academy at 4 weeks after treatment.

Patient satisfaction with the treatment according to the Roles and Maudsley scale was excellent ("1") or good ("2") in 82.6% of patients in the ESWT group at the end of follow-up, compared to 36.8% of patients in the exercise-only group. The difference was statistically significant ($p = 0.002$) (Fig. 4).

No complications or significant adverse effects were observed in either group.

4. Discussion

Military cadets are regularly subjected to training regimes with

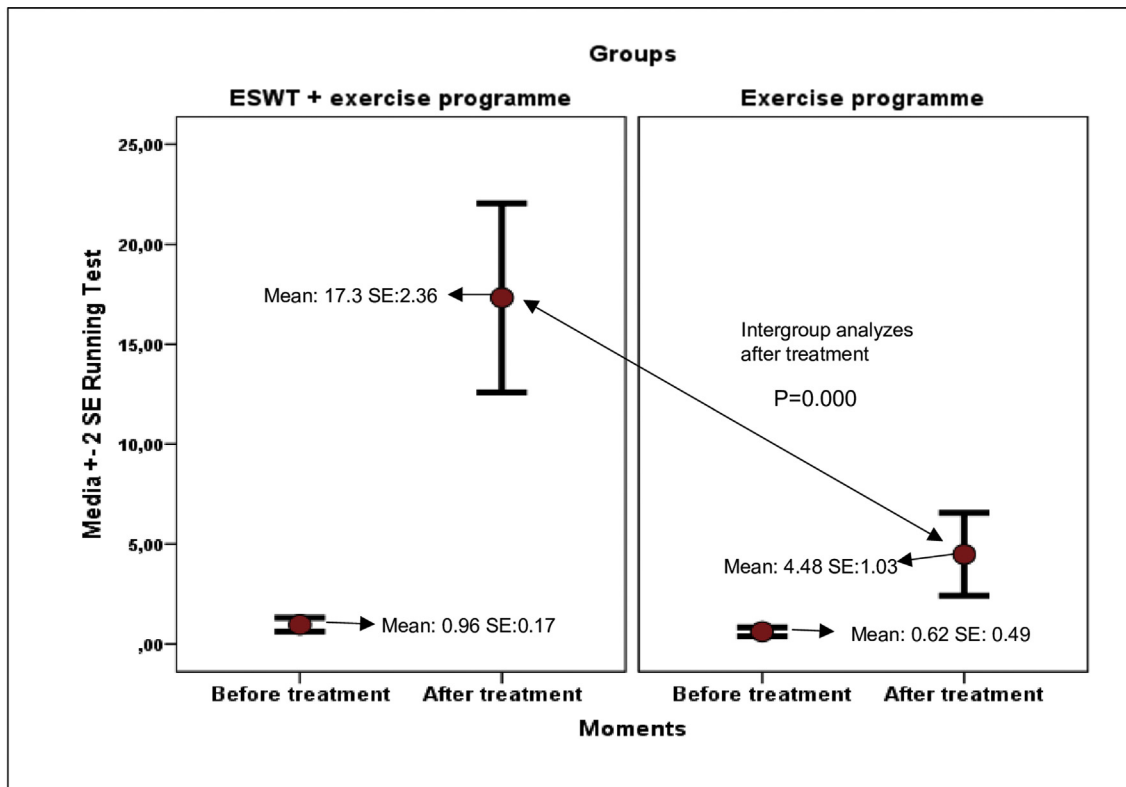


Fig. 3. Running time in minutes in both groups.

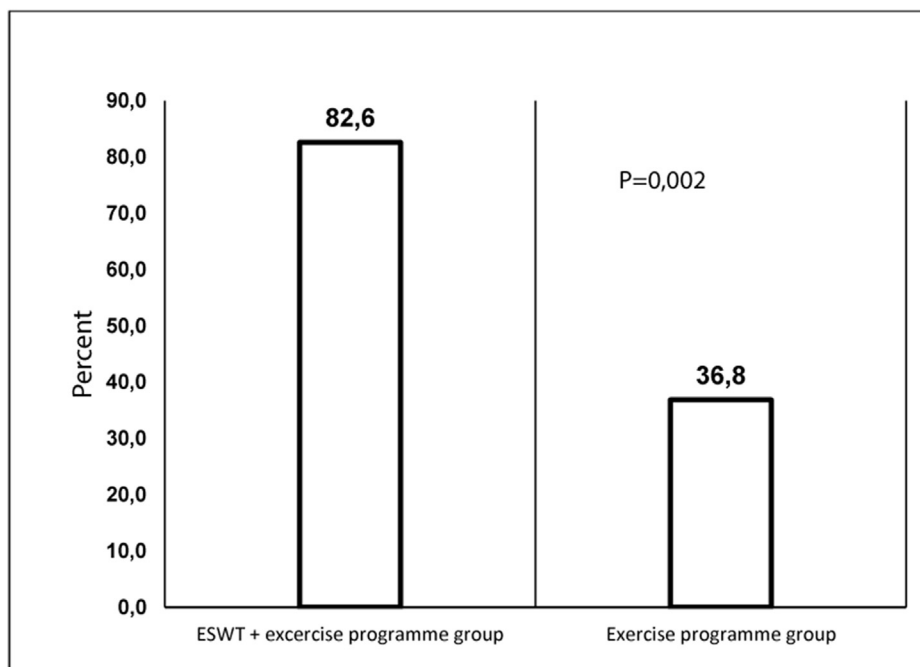


Fig. 4. Excellent or good results according to Roles and Maudsley scale on last follow-up in both groups.

intense periods of physical activity, overload of the lower limbs, and sometimes with insufficient recovery periods, which may lead to musculoskeletal lesions such as MTSS. Treatment of MTSS using ESWT has been shown to be effective in athletes [48,49], but its efficacy in military personnel has not been evaluated to date (Table 4).

The main result of our study shows that the use of focused ESWT plus exercise in military cadets was more effective, as measured by clinical and functional outcome measures, than exercise alone, particularly in terms of pain experienced after running, running time and patient satisfaction with the treatment according to the Roles and Maudsley scale.

In our study, pain-free running time increased in both groups at the end of follow-up and was significantly higher in the ESWT group. Rompe et al. [48], in a non-randomized retrospective study, showed pain alleviation in the radial shockwave group compared to the control group, consisting of rest, cryotherapy and a regime of

therapeutic exercises carried out at home. They also demonstrated that ESWT was associated with a faster return to sports activities: in 64% of athletes after 4 months of treatment and 85.1% after 15 months, compared to 46.80% of controls after 15 months.

In our study, patients in the ESWT group were able to run without pain for 17 min 33 s at one month after treatment, much longer than the 4 min 49 s in the exercise-only group.

Similarly, Moen et al. [49], in a non-randomized, non-blinded observational study in MTSS, showed that 5 sessions of focused ESWT significantly shortened recovery time to 59.7 days, compared to 91.6 days for the patients in the control group.

We used the same device as Moen et al. [49] and Newman et al. [50] to generate focused electromagnetic ESWT to treat MTSS, as well as the same type of functional evaluation, the running test. This test was chosen because running is one of the essential training activities of military cadets.

Surprisingly, Newman et al. [50], in a randomized, double-blind

Table 4

Evidence on shockwaves in medial tibial stress syndrome.

Author (year)	Type of Study (No. of Patients)	Device	No. of Pulses	EFD	Frequency (Hz)	No. of Sessions	Main Results
Rompe et al. (2010) [48]	Retrospective cohort, in athletes N = 94	Radial	2000	2.5 bar	8	3	Recovery level: Completely recovered or much improved: ESWT 76% vs. Control 37%.
Moen et al. (2012) [49]	Prospective observational, non-randomized, in athletes N = 42	Focused	1000 –1500	0.10 –0.30 ^a	2.5	5	Time to full recovery: ESWT 59.7 days vs. Control 91.6 days.
Newman et al. (2017) [50]	Prospective RCT, in athletes N = 28	Focused	1000 –1500	0.10 –0.30 ^a	–	5	- No significant differences between groups during muscle pressure, during running. - No differences in running pain-limited distance. - Self-perception of change GROCC: no significant difference between groups.
Gomez et al. (2017) [58]	Prospective RCT, in military personnel N = 42	Focused	1500	0.20 ^a	5	1	- Lower pain (VAS) after running in ESWT + exercise programme of 2.17 vs. 4.26 in the exercise programme group. - Faster running time in ESWT + exercise programme of 17.33 min vs. 4.49 in the exercise programme group. - Excellent or good results in 86.2% in ESWT + exercise programme compared to 36.8% in exercise programme group.

^a mJ/mm²; EFD, energy flux density; ESWT, extracorporeal shockwave treatment; RCT, randomized clinical trial; GROCC, Global Rating of Change score.

study in patients with MTSS treated with an electromagnetic device, found no significant differences between the treatment group and the control group in terms of pain at rest, on muscle palpation, while running or in pain-free running distance. These results are different to our results and there are several possible causes for this: 1) no complementary investigations were performed in MTSS patients to rule out other conditions, such as stress fracture, which require different treatment and longer recovery times; 2) the small sample size of 28 patients initially and 24 at the final follow-up; 3) non-adherence to ISMST standard [54], given that EFD was increased from 0.1 to 0.3 mJ/mm² in each session, instead of a specific therapeutic energy level; treatment was performed every two weeks, instead of weekly; 4) the “sham” dose consisted of 1000 pulses of 0.01 mJ/mm² in each session, which may have had a positive therapeutic effect. These circumstances may explain why there were no differences in the ESWT group compared to the sham group.

Standard electromagnetic ESWT parameters recommended are 1200–1500 pulses, EFD = 0.18–0.25 mJ/mm² and 3 or 4 treatment sessions [55]. In our case, our ESWT protocol consisted of 1500 pulses, EFD 0.20 mJ/mm² in a single session. Cadets with MTSS were able to resume their activity in a safe and effective manner within the shortest time possible. Other pathologies, such as plantar fasciitis, have been treated with one session of electromagnetic ESWT with favorable results [56,57]. Unlike other studies, we showed that a single session of focused shockwaves produced excellent or good results in 82.6% of patients one month after treatment [58]. In contrast, in the studies by Rompe et al. [48], Moen et al. [49] and Newman et al. [50], (Table 4). MTSS patients required, respectively, 3, 5 and 5 ESWT sessions. Shorter recovery time is important in military personnel with MTSS, so that they can return to their functional activities quickly. On the other hand, compliance with the training exercise programme was confirmed at the end of the study by all patients in both groups.

Another important aspect associated with this condition is the body mass index. Unlike the study by Plisky [59], our study shows no significant differences in this variable, probably due to the fact that, in military training, the intense aerobic physical exercise required by the cadets makes them more likely to be in good physical condition and not overweight or obese. This observation supports the hypothesis that the condition is due to repeated overloading of the cadets' leg bones during the period of military training, not to excess weight.

MTSS tends to become chronic and may lead to a stress fracture of the tibia [5,22], which could end a patient's military career due to the long time to functional recovery. A cost study would presumably show that a single session of focused electromagnetic shockwaves is more efficient in improving symptoms and reducing the time to functional recovery than multiple physiotherapy sessions. We therefore believe that focused shockwaves in MTSS are safe, effective and efficient, shortening the time required to achieve functional recovery compared to conventional therapies.

We must consider that the current study included military personnel of both sexes and there were no age group differences. Therefore, the findings of this study could be generalized to the population of military cadets and patients with MTSS as well.

Limitations of our study are small sample size and short follow-up. Further research is required to establish long-term ESWT cost-effective interventions in MTSS patients for a safer and faster functional recovery to their previous activities.

5. Conclusion

A single application of focused extracorporeal shockwave treatment in combination with a specific exercise programme

accelerates clinical and functional recovery in military cadets with MTSS, with a success rate of 82.6% at 4 weeks.

Conflicts of interest

Nothing to declare.

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Ethical approval

The research project was approved by the ethics and research committee of Hospital Militar Central de Colombia (Ref. 7257/DIGE/16/09/2014). The study was carried out in line with the principles of the Helsinki Declaration and best clinical practice.

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Author contribution

Santiago Gómez García: coordination, design of the study, data collection, interpretation of data, writing the article, tables, final revision.

Silvia Ramón Rona: writing, figures, tables, final revision.

Martha Claudia Gómez Tinoco: data collection, writing, final revision.

Mikhail Benet Rodriguez: design of the study, statistical analysis, interpretation of data.

Diego Mauricio Chaustre Ruiz: data collection, revision.

Francía Piedad Cárdenas Letrado: data collection, revision.

África López-Illescas Ruiz: final revision and correction.

Juan María Alarcón García: final revision and correction.

Guarantor

Santiago Gómez García.

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