The additional value of a pneumatic leg brace in the treatment of recruits with medial tibial stress syndrome; a randomized study

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Abstract

Objective: To study the additional effect of a pneumatic leg brace with standard rehabilitation for the treatment of medial tibial stress syndrome (MTSS) in recruits.
Methods: In a single blinded randomized study, 15 recruits (age 17-22) followed a rehabilitation programme consisting of leg exercises and a graded running programme. Recruits performed daily exercises and ran three times a week. The running programme consisted of 6 consecutive phases. One group was, after randomization, additionally provided with a pneumatic leg brace. Follow-up was provided every other week. Days to completing the running programme was the primary outcome measure, the Sports Activity Rating Scale (SARS) score and satisfaction with the treatment were secondary outcome measures.
Results: In total 14 recruits completed the rehabilitation programme. No differences were found in the number of days until phase six of the running schedule was finished between the brace and the control group (Brace 58.8 ± 27.7 (mean ± SD) vs Non-Brace 57.9 ± 26.2 (mean ± SD, p = 0.57). Also no differences were found in the SARS scores between the groups. Overall satisfaction with the treatment was 6.4 ± 1.1 (mean ± SD) on a 1-10 scale for the brace group and 7.1 ± 0.7 (mean ± SD) for the control group (p = 0.06). Comfort of the brace was assessed as 4.8 ± 1.3 (mean ± SD) on a 1-10 scale.
Conclusions: No additional large effect of the pneumatic leg brace could be found in recruits and wearing of the brace was not feasible, since the wearing comfort was low.

Introduction

Medial tibial stress syndrome (MTSS) is one of the commonest causes of exercise-induced leg pain [1]. Incidences varying from 4-35% are reported, with both extremes being derived from military studies [2-4]. The most commonly accepted definition is that provided by Yates and White [4]: "*exercise induced pain in the leg on the posteromedial side of the tibia and in addition pain on palpation of the posteromedial tibia for at least five centimetres*", and despite incidences of up to 35% a recent systematic review reported a lack of good quality studies on the treatment of MTSS [5]. All three studies reviewed were performed in a military setting and were of poor quality [2,6,7]. The review reported that no treatment has been shown to be superior to rest alone and it was suggested that clinical trials should be performed on the treatment of MTSS. The same review proposed that MTSS is a problem of bony overload [5]. There are four important findings that support the theory that bony overload forms the primary patho-physiological basis for MTSS. Firstly, on triple phase bone scans the last phase is abnormal, showing that the bone and periosteum are involved [8,9]. Secondly, on high resolution CT-scans, although rarely performed for this indication clinically, the tibial cortex is found to be osteopenic, as can be seen in patients as well as in asymptomatic athletes as a sign of bone remodeling [10]. On MRI images bone marrow oedema as well as a signal along the periosteum can be seen [11,12]. Fourthly, in patients with MTSS bone mineral density is reduced when compared to controls [13]; when symptoms improve the bone density returns to normal [14]. These findings suggest that the pathology of MTSS may be similar to tibial stress fractures where a similar but wider signal can be seen on bone scans and MRI images [11,15].

Since bony overload is believed to be the underlying problem in MTSS, treatment options for stress fractures, such as a pneumatic brace, could also be useful in MTSS. Since the 1980's two case series and three randomized controlled trials, some of which were conducted in the military setting [16-20], have been published. All except for Allen et al [16], showed a promising effect of the pneumatic leg brace in the treatment of tibial stress fractures. A 2005 Cochrane review concluded that rehabilitation of bony overload injuries may be aided by the use of a pneumatic leg brace [21]. The present study examined the role of a pneumatic brace in addition to a standard rehabilitation protocol in recruits with MTSS, with the working hypothesis that the addition of the brace would significantly reduce the time taken to complete a standard rehabilitation programme and produce a faster functional recovery.

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Methods

Following local medical ethical committee approval, male soldiers (age 17-22 years) were recruited from two bases of the Royal Dutch Army between October 2008 and June 2009. All subjects had previously been withdrawn from basic army training and placed into a remedial platoon and referred by an army physician to our trained investigator with a suspected diagnosis of MTSS. Patients were included by the investigator if they fulfilled the inclusion criteria and gave their informed consent. The inclusion criteria were: exercise induced pain in the leg on the posteromedial side of the tibia and pain on palpation of the posteromedial tibia for at least five centimetres [4] for at least two weeks. Patients were excluded if there was suspicion of a tibial stress fracture, compartment syndrome or tibial fracture in the past. When X-rays showed tibial stress fracture or compartment pressure measurements revealed compartment syndrome patients were excluded.

Phase	Surface	Minutes								Total	Speed / intensity
1	Treadmill	2	**2**	2	**2**	2	**2**	2	**2**	16 min	2 is running 10 km / hour **2** is walking 6km / hour
2	Treadmill	2	**2**	2	**2**	2	**2**	2	**2**	16 min	2 is running 12 km / hour; **2** is walking 6 km / hour
3	Grass	3	**2**	3	**2**	3	**2**	3	**2**	20 min	Intensity 1-2 * 3 is running; **2** is walking
4	Road	3	**2**	3	**2**	3	**2**	3	**2**	20 min	Intensity 2, 3* is running; **2** is walking.
5	Road									16 min	Intensity 2*.
6	Road									18 min	Intensity 2/3*.

Table 1: The rehabilitation running program. *Intensity ratings: Intensity 1 = light jogging, Intensity 2 = jogging while able to speak, Intensity 3 = jogging while speaking becomes difficult.

Procedure

Patients were randomly assigned by sealed envelope selection, to one of the two available treatment arms: standard rehabilitation programme or standard programme plus the use of a pneumatic leg brace. Individuals were always kept in different rehabilitation groups to other trial participants to ensure they were blinded to the recovery of other participants. Baseline demographic and comorbidity data was obtained as well as a baseline measurement of outcome parameters.

Running test

At baseline all patients performed a running test to assess severity of MTSS and determine the starting point of the rehabilitation program. Before the test, the researcher explained that significant pain was defined as more than ten consecutive strides whereby the pain was rated at 4 or more on a 0-10 pain scale. The test consisted of 2 minutes walking on a treadmill at 7.5km / hour before increasing to 10km / hour at which point running commenced. The patient stopped running when the specific 'MTSS' pain was felt in the leg on the posteromedial side. The distance run without pain at 10km / hour was recorded. No running test was performed, when pain was present during walking.

Baseline Treadmill result (Distance in metres) without pain at 10km/h	Commencement Phase of Rehabilitation Programme
Pain during walking	No running – exercise schedule only
1-400	Phase 1
401-800	Phase 2
801-1200	Phase 3
1201- 1600	Phase 4
>1600	Phase 5

Table 2 The relationship of baseline treadmill result to phase of commencement of rehabilitation programme

Standard Rehabilitation Programme

The starting point of the rehabilitation protocol (Table 1) was determined by the results of the treadmill running test (Table 2). When pain was present already during walking no running test was performed and the subject started with the exercise schedule. Supervised running on the treadmill was performed three times a week with at least one day rest in between.; when symptoms improved, running outside was no longer supervised. Recruits were instructed to run until they experienced leg pain ≥ 4 / 10 on the 1-10 pain scale. When a rehabilitation phase was completed without pain and there was no pain both immediately after running and on the following day, the recruit moved up to the next rehabilitation phase. When Phase six was completed without pain, the recruit was considered to be recovered. When pain was present (≥ 4 / 10) during running or shortly thereafter, the running was stopped and the next run was started at the start of the same phase. When the recruit had just started a new phase and pain was experienced during running, the recruit was returned to the previous phase.

Apart from running, the patients performed exercises five times a week, supervised by a military instructor. These exercises consisted of stretching, strengthening and ankle stability exercises. Five different phases of the exercises existed, which were increasingly tough to perform. When one phase of the exercises was finished without pain (≤4/10) the next phase could be commenced the next day. The exercises were first demonstrated by a therapist and printed instructions given to the patients. The patients conducted the exercises with an army supervisor present, who was trained and instructed for this task.

Both groups followed the same rehabilitation protocol, the only difference being that one group also received a pneumatic leg brace (Aircast Inc., Summit, New Jersey, USA) (Figure 1) to wear during running. The size of the brace was fitted to the length and width of the patients lower leg. The patients were instructed to wear the

Figure 1 : The pneumatic leg brace worn by the recruits.

brace while performing the running schedule. When pain was present during ambulation patients were instructed to wear the brace all day, but not during the night. Additional information was provided by the investigator in order to prevent blisters and friction wounds which could occur while wearing the brace.

Outcome measurements

The recruits were assessed every two weeks by a blinded investigator - the primary outcome measure was the time from beginning rehabilitation to completing Phase 6 of the running program without pain. Secondary outcome measures were the Sports Activity Rating Scale (SARS) score [22] in which functional activity is expressed on a 0-100 scale, where 0 = severe complaints in daily activities and 100 = no complaints during heavy sport activity, overall satisfaction with the treatment and comfort of the brace to wear. The overall satisfaction with the treatment and the wear comfort of the brace were expressed on a 1-10 score (1= very low, 10= very high). A score of 7 or higher was assessed as feasible. Compliance was looked at by the investigator, who checked compliance diaries that the patients kept.

Statistical analysis

Based on previous studies using a pneumatic brace for stress fractures in the leg [16-20] we believed we would find a large effect of the brace. Based on a 80% power to detect a significant difference (p = 0.05) 7 patients were required in each study group. The researchers analyzing the data (MM and EB) were blinded to the treatment allocation and had no contact with the patients. Data were analyzed using SPSS version 15 (SPSS Inc, Chicago, Illinois, USA). Groups were compared using the Independent Samples T-Test or, in case of skewed distributions, the non-parametric Mann–Whitney U Test. For loss to follow-up the intention-to-treat principle was used.

Results

From October 2008 until June 2009 15 military recruits were included in the study. The progress of the patients in the study, including withdrawals from the protocol, is shown in Figure 2. One patient in the brace group was excluded from the study; thus data from 14 patients were available for the intention-to-treat analysis.

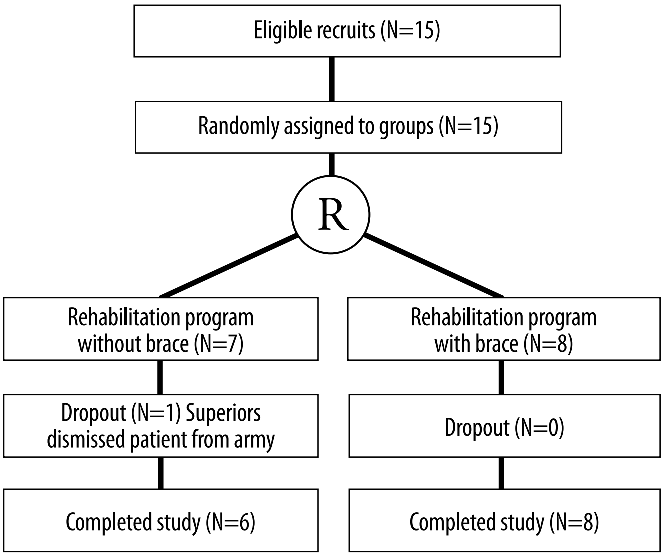

Figure 2: Flow diagram presenting the progress of the recruits in the study, including withdrawal from the protocol. ® = random assignment to study groups. The flow diagram is based on CONSORT guidelines [23].

Baseline values for age, body mass index, distance in meters on the running test, SARS score and duration of symptoms at inclusion were not statistically different between the control group and the brace group (Table 3).

Groups	**Brace (N=8)**	**No brace (N=7)**	**p-value**
	Mean ± SD	Mean ± SD	
Age (years)	19.1 ±1.9	18.6 ±1.2	0.62
Body mass index (BMI)	24.5 ± 2.0	23.1 ± 2.0	0.25
Metres on treadmill before developing pain	854.3 ± 490.4	734.8 ± 626.9	0.96
Duration of symptoms (days)	32.9 ± 20.2	35.1 ± 16.9	0.83
Sports Activity Rating Scale (SARS) score	75.7 ± 21.3	74.3 ± 10.2	0.44

Table 3: Baseline characteristics of the recruits with MTSS.

No significant difference was found in the primary outcome measure, the number of days to complete the running schedule between the brace and the control group (Brace 58.8 ± 27.7 days (mean ± SD) vs non-brace 57.9 ± 26.2 p = 0.57). No significant difference was found in the secondary outcome measures. The SARS scores were not significantly different between the two groups at baseline (p = 0.44) and after the rehabilitation running schedule (p = 0.17). Both groups showed a significant improvement in SARS score after completing the running schedule (brace group p = 0.02, no-brace group p = 0.0004). The other secondary outcome measure, overall satisfaction with the treatment, was not significantly different either (6.4 ± 1.1 on a 1-10 scale for the brace group and 7.1 ± 0.7 for the control group (p = 0.06)). Wear comfort of the brace was assessed as 4.8 ± 1.3 (mean ± SD). At follow-up after six months no recruit reported having developed symptoms of MTSS again after they were free of symptoms.

Complications / compliance

All but one recruits (86%) wearing the pneumatic leg brace mentioned complaints while wearing the brace, consisting of pain around the ankle. On follow-up small wounds and shafting were regularly seen around the lateral and medial malleolus. The complaints could only partly be solved by filling the brace with more air and by applying tape on the edges of the brace where it could be sharp. Nonetheless, compliance of wearing the brace was good.

Discussion

This study showed that for recruits, there was no additional value in using a pneumatic leg brace in the treatment of MTSS as measured by days to completion of a running program. In addition, the wearing comfort and thus the feasibility of the brace for the recruits, was low. Our power calculation was based on data from trials of pneumatic leg brace in tibial stress fractures [16,18,19], two of which showed a reduction in time to completion of rehabilitation of more than 55 days [18,19]. We assumed a comparable but lesser reduction of 30 days to complete our rehabilitation programme using the brace, therefore the study was only powered to detect a large difference in outcome and was planned as a potential pilot study – further, larger studies would be needed to demonstrate smaller treatment effects of the brace on MTSS.

The theory underlying our trial is the belief that MTSS forms part of a spectrum of disease with tibial stress fractures [5] and that there is evidence [24,25] that a pneumatic brace is of value in treating fractures, confirmed in a Cochrane review [21].

Dickson and Kichline studied ten female athletes with tibial stress fractures, diagnosed with radiographs or bone scans [17]. The athletes received a pneumatic brace and were immediately able to compete at the same level as before the onset of symptoms. All were asymptomatic in less than one month. Whitelaw et al. [20] also used a pneumatic brace for the treatment of tibial stress fractures. Seventeen men and women were included, after establishing the diagnosis with radiographs and bone scan. These patients were able to perform intensive training after 3.7 weeks (range 3-6 weeks) and were able to return to competition at the pre-injury level after 5.3 weeks (range 4-7 weeks). A randomized controlled trial by Swenson and colleagues in 1997 studied 18 athletes with tibial stress fractures [19]. All patients, men and women, had positive bone scans correlating to the painful site and after 12 weeks, 94% of the radiographs showed positive signs of a stress fracture. After random selection, one group received a pneumatic leg brace while the control group did not. The median number of days until the start of light activity was significantly lower in the brace group (p=0.017) compared to the control group (7 versus 21 days). The median number of days from treatment initiation to recovery was 21 ± 2 (SD) for the brace group and 77 ± 7 (SD) for the control group (p=0.0005). It is of note that this study was small and that in the control group more women were present. An Australian military study included 60 patients and allocated them randomly to an pneumatic brace group or a six weeks convalescent leave group. The last group was given non-impact exercise advice. After either wearing the brace or convalescent leave, both groups joined a standardized rehabilitation protocol. A significant difference was found in the number of lost training days (12.3 ± 21.1 days vs 72.4 ± 45days; p <0.0001) in favour of the use of the brace [18]. The most recent randomized study was performed in the military and showed no difference in the time taken to be able to run 1 mile pain free (p = 0.24). Of the 31 included patients only 20 of them completed a rehabilitation program (10 with pneumatic leg brace, 10 without brace) [16]. Recently, in a randomized trial, Johnston et al. studied the effect of a non-pneumatic brace on the recovery of MTSS in a military population [6]. They could not find an aided effect of their brace compared to a control group.

One proposed mechanism by which a brace may be useful is by increasing the resistance to torque, as was shown in an animal study with canine tibial fractures by Dale et al. [24]. In this way less bowing of the tibia may be the result as other studies have shown that increased bowing leads to increased microdamage of the bone [26,27] .

One limitation of our study is that subjective assessment of leg pain was used throughout baseline testing and rehabilitation to decide starting rehabilitation phase and phase progression through the rehabilitation schedule. Consequently, not all patients progressed to a next phase of the running schedule having the same sensation in the legs. Furthermore no validated score is available for MTSS, so progress or worsening of symptoms is hard to measure. The development of such a score would greatly ad the study of MTSS in the future. It is also of note that in our study recruits were not supervised beyond Phase 2 of the running schedule which may have reduced recruit compliance.

Conclusion

This randomized study failed to show the predicted large benefit of adding a pneumatic leg brace to the standard rehabilitation protocol in the treatment of MTSS in military recruits. Reported comfort levels with the brace were low. Despite these negative findings we would recommend further research with a pneumatic brace in the treatment of MTSS, given the better results found in other randomized studies in the treatment of leg related bony overload conditions.

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