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Hyperthermia at 434 MHz in the Treatment of Overuse Sport Tendinopathies: A Randomised Controlled Clinical Trial

Abstract

The objective of this randomized study was to compare a thermotherapy system, hyperthermia at 434 MHz and conventional ultrasound in the treatment of overuse sports tendinopathies. The study group consisted of 44 athletes, 33 males and 11 females (age 26 ± 4.56 years) affected by tendinopathies at lower extremities (patellar or achilles tendons). After elucidation of the kind of trial, 22 patients were randomly assigned to hyperthermia and 22 to ultrasound. The patients received after a pain measurement and ultrasound scanning 12 treatments, 3 times a week for 4 weeks. The same standardized examination was done at the end of treatment and 1 month after the end of treatment. The assessor physician was unaware of the treatment allocation. The patients were asked to rate the ultimate outcome on the base of pain resolution and return to sports activity. Both groups had a significant decrease of symptoms ($P<0.001$). Hyperthermia, however, demonstrated better effects on the reduction of VAS score and on the subjective overall satisfaction (77%) of excellent and good results in comparison to the 33% of ultrasound. In patients with chronic overuse tendinopathies hyperthermia at 434 MHz showed encouraging results, with short-term clinical improvement, safety and no side effects.

Key words
Overuse injury · ultrasound · physical therapy · microwave diathermy · achilles tendon · patellar tendon

Introduction

Overuse tendinopathies are a major problem for athletes and active patients alike. A wide variety of modalities including ultrasound, laser and different forms of heat are separately or in combination employed to treat these conditions [10,15,27]. Such modalities are claimed to decrease inflammation and pain and promote healing processes, but there is no definite evidence to support many of these claims [4,20].

One of the most recent and promising thermotherapy systems is the hyperthermia which, using a superficial cooling system and a deep heating source operating with a microwave power generator at 434 MHz, allows the target tissue to rise therapeutic temperatures (between 41 °C and 45 °C) down to a depth of several centimetres without overheating the overlying superficial tissues [24]. The effectiveness of hyperthermia in the early treatment of muscle injuries in athletes has been recently demonstrated [14]. The aim of our study was to investigate the efficacy of hyperthermia in the treatment of overuse tendinopathies. In particular, as ultrasound is a widespread modality used in the treatment of tendon injuries for its thermal, mechanical and analgesic effect [11,15,21,26], we included a control group treated with conventional ultrasound in the study described here. To date, there have been no clinical studies in scientific literature on the use of hyperthermia at 434 MHz in the treatment of overuse tendinopathies.

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Materials and Methods

During the period between April 1998 and January 2000, 44 athletes (33 males and 11 females), all engaged in competitive activity with a mean age of 26 ± 4.56 (range 17 to 35) affected by overuse tendinopathies at lower extremities (patellar and Achilles tendons) were recruited at the Physiotherapy Department of the Institute of Sports Science. Clinical history and physical examination were chosen as a criteria of inclusion to make a diagnosis of patellar or Achilles tendinopathy. The subjective history of all patients included reports of pain initially related to activity levels especially repetitive ballistic movements of the knee and ankle joint and then affected daily activities like ascending and descending stairs; the duration from the onset of symptoms until the start of the treatment varied from 6 weeks to 72 weeks, on average. The most reliable clinical finding in patellar tendinopathy was pain and tenderness by palpating the tendon with the knee fully extended; the signs of Achilles tendinopathy were conversely pain and tenderness on palpation at the mid-portion of the tendon or at distal insertion with the patient lying prone, knee fully extended and the ankle in slight dorsiflexion, associated with tendon swelling (diffuse or localized).

The athletes treated with other forms of physical therapy or medication within the last 5 weeks preceding the trials, with documented patello-femoral pathology, severe lower limb malalignment, associated meniscal or capsulo-ligamentous injury, calcific tendinopathy, Haglund's syndrome or other systemic diseases involving patellar and achilles tendons were excluded. The stage of patellar and Achilles tendinopathies was classified according to Bonar's classification of overuse tendon condition [20] (Table 1). The right knee was involved in 20 cases, the left knee in 18 cases and 3 had bilateral involvement. The patients were informed that this was a randomized study and they would be allocated into one of the two treatments. After informed consent the participants were block randomized with a computer-generated schedule into two groups. Neither patients nor outcome investigators were aware of the kind of treatment received. The first group (N = 22) with a mean age of 26 ± 3.48 (range 20 to 32) was treated with hyperthermia at 434 MHz. The second group (N = 22) with a mean age of 26 ± 5.5 (range 17 to 35) was treated with ultrasound. There was no significant difference between group A and B as regards to age (P = 0.0001). All the patients underwent a clinical and instrumental evaluation. Subjective pain during local manual pressure in the area of maximum tenderness of the tendons and during isometric contraction against resistance of the quadriceps and gastrocnemious muscles were measured with a 10 cm horizontal analogue scale (V.A.S.: 0 = no pain, 10 = incredibly severe pain). The average of three ratings was taken as the best estimate of current pain on each subject. An ultrasonographic evaluation using a linear-array transducer (Esaote Biomedica AU4 idea) at 7.5 MHz was performed in all the patients by the same radiologist (S D) to detect any abnormalities in the morphology and echostructure of the tendons. All patients were clinically and instrumentally assessed before starting the treatment, at the end (four weeks) and one month after the end of treatment. Both groups received 12 treatments three times a week, for four weeks, 30 minutes long for the first group and 15 minutes long for the second group. Hyperthermia treatment was administered, after the proper positioning of the thermocouple that is, orthogonal to the electromagnetic field and in the point of maximum tenderness of the tendon (Fig. 1), at a setting of 20–25 watt, a pilot temperature of 42 °C and the water bolus temperature in a range of 39–40 °C, according to the superficial target to be irradiated and to the subcutaneous fat thickness. The threshold of thermal pain that corresponds to a skin temperature of about 45 °C [16] was never exceeded in any of the patients. Continuous ultrasound therapy was conversely delivered in circular fashion, using an intensity of 1.5w/cm^2. A gel couplant was placed between the ultrasound transducer and the tendon area. At the end of treatment patients were asked to rate the results of their treatment according to the presence of pain and return to the specific sport activity. Patients rated the outcome of each treatment as excellent if the pain had been completely relieved with a full return to their preinjury sport level; patients rated as good, if they had a full return to sport but with occasional discomfort during maximal exertion; patients rated as fair, if they had discomfort, drastic reduction of training and interruption of competitive activity; patients rated as poor, if they had given up their own sport and had continuous symptoms, also in activity of daily living.

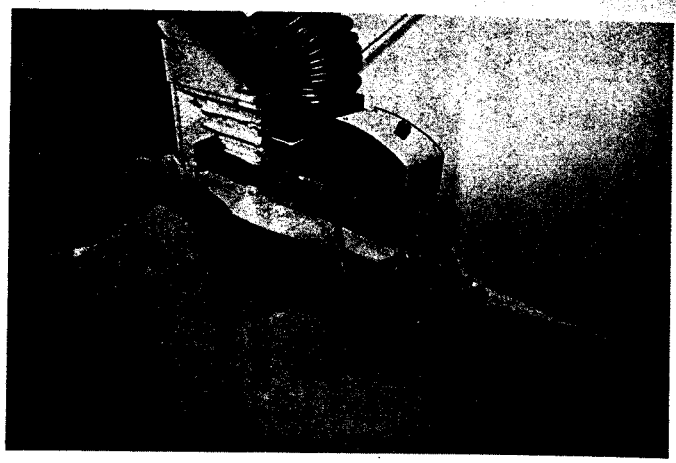

Fig. 1 Application of hypertermia in a case of patellar tendinopathy.

Table 1 Stage of patellar and Achilles tendinopathies according to Bonar's Classification

Pathologic Diagnosis	*Site*	*N*
Tendinosis	Body	6
	Patellar	
	Osteotendineous insertion	7
	Body	14
	Achilles	
	Osteodineous insertion	7
Partial rupture or tendinitis	–	–
Paratenonitis	–	–
Paratenonitis with tendinosis	Achilles	10

Statistical analysis

Means and standard deviations were calculated for all subjects in each group, for each parameter by a statistician who was unaware of treatment allocation. A Student's t-test was used to compare the before and after treatment values of VAS score among the two groups.

Table 2 Results of V.A.S. score before and after treatment, percentage (%) of improvement with each treatment

	Pain on manual pressure before	Pain on manual pressure after	% improvement	Pain on isometric contraction before	Pain on isometric contraction after	% improvement
Hyperthermia Mean ± SD	6.9 ± 1.7	1.9 ± 1.4	72.2	3.9 ± 2.8	1.1 ± 1.7	72.0
Ultrasound Mean ± SD	5.6 ± 1.9	4.0 ± 1.9	29.1	3.0 ± 1.7	1.7 ± 1.5	43.2
P<		0.0001			0.0001	

A $p < 0.0001$ was considered statistically significant. An unpaired t-test was used to determine which of the treatments was more effective on the resolution of symptoms and resumption of sport activity.

Characteristics of deep heating modalities

Hyperthermia

An "ALBA Hyperthermia System" (RESTEK SRL ITALY) was used. It was equipped with a 434 MHz microwave generator with a maximum output power of 100 W; a microstrip antenna applicator, with a curve shape specific for semicylindrical joint volumes of 20–30 cm^2 diameters, total size of 196 cm^2 and an effective field size of 96 cm^2 (EFS = 50% SAR on the surface); a bolus of dielectrical material (silicone), filled with thermostatic deionized water that allows to achieve the greatest energy transfer while preventing the overheating of superficial tissues near to the radiant source; a hydraulic complex of thermoregulation, whose function is to keep water temperature between 30 and 42 °C; a skin temperature sensor, measuring skin temperature in touch with the bolus. The safety system is developed under specifications given by the EEC (European Community Countries) 93/42 rules for the class II B apparatuses. The system is programmed to stop supplying electromagnetic energy in case of temperature sensor breaking, malfunction at the control power generator, damage at any of the components of the computer control hardware or excessive exposure of radiofrequency on the environment.

Ultrasound

A Level 730 device (Mettler Electronics Corporation USA) was used. It was equipped with an emission probe of 3.2 MHz frequency with an effective radiating area (E.R.A.) of 5 cm^2 and a maximum output power of 22 W.

Results

Effectiveness of each treatment

The analysis of effect of each treatment showed a statistically significant reduction of the VAS scores concerning the measures of pain pressure (ultrasound: T = 3.9, p = 0.001; hyperthermia: T = 14.8, p = 0.0001) and pain on active contraction in both groups (ultrasound: T = 4.6, p = 0.0001; hyperthermia: T = 6.2, p = 0.0001) (Table 2).

Comparison between treatment groups

The results showed a significant difference between the two treatments. Hyperthermia expressed a better effect on the reduction of the VAS scores as regard as to pain pressure (T = 6.3, p = 0.0001) and pain on active contraction (T = 2.8, p = 0.007). The distribution of outcomes based on the subjective global assessment of the effect of the treatments (Fig. 2) showed a significant improvement of hyperthermia (77% of cases with excellent and good results, over ultrasound 33%).

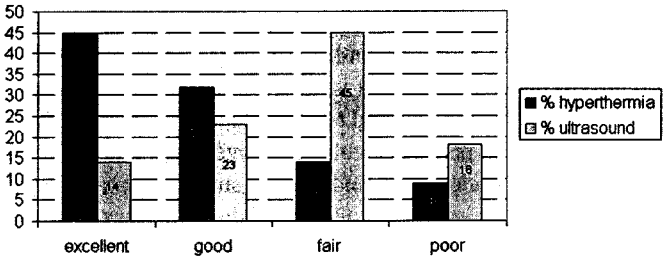

Fig. 2 Distribution of subjective global assessment of hyperthermia and ultrasound.

Discussion

Overuse tendinopathies account for a substantial proportion of overuse injury in sport [4,19,34]. They are not only restricted to competitive athletes but affect also amateurs and many working people. At the present state of knowledge, a lot of questions regarding the rationale for their treatment, especially in regard to the role of physical modalities, remain unanswered [3,12,15,27,33]. Some of the factors that may interfere with optimal treatment are that overuse tendinopathies have a multifactorial etiology, they are considered as an inflammatory disease while most of the studies comparing surgical specimens and histopathological findings revealed that these conditions are the result of a degenerative tendinosis and a collagen breakdown [2,5,6].The use of deep heating modalities, because of their beneficial effects of increased circulation and cellular metabolism resulting in a greater exchange of wastes and nutrients in a specific area, has long been accepted as a part of the treatment of overuse tendinopathies [28,17]. The hyperthermia systems were applied in the oncological field more than 30 years ago and are still employed especially in addition to radiotherapy in the treatment of different superficially located tumors [13,25], but only from 1994 have they been introduced in Italy and in some of the European Community Countries as a therapeutic modality for clinical use in physical medicine and sports traumatology [8,14]. These technologies are supplied with a microwave power generator at 434 MHz, an applicator at 434 MHz with a water bolus, a temperature – control for noninvasive or invasive (oncological use) measurement and appropriate software to control and memorize the temperature reached in the treated target; the hyperthermia systems are able to reach therapeutic temperature between 42°–45 °C, in delineated target volumes of approximately 100–200 cm^3, from 1 to 4 cm in depth, keeping the

skin temperature under 36 °C [9,24]. Our controlled randomized study between hyperthermia at 434 MHz and conventional ultrasound showed that hyperthermia at 434 MHz and ultrasound produce a statistically significant reduction of the pain on manual palpation and on isometric contraction, as quantified by the VAS subjective assessments [18]. Both treatments alleviated symptoms in the short-term, even if the hyperthermia group had significantly better results on the remission of symptoms during isometric contraction and on the rate of overall outcome satisfaction when compared with ultrasound (Fig. **2**). In our study, the ultrasonography imaging was unable to demonstrate significant changes of tendon structure in both the treated groups, due to its technical and diagnostic limitation and probably to the short follow-up. It is very well known that the complete healing of a degenerated tendon can take several weeks or months due to its poorer vascularity, oxygenation and nutrition compared to muscle tissue and several substrates and physiological factors can influence collagen production in regenerating tendons [5,6,11,19]. Despite these facts, many authors have suggested that in chronic tendinopathies the healing process is best indicated by relief of pain and return to function and abnormal imaging was absolutely compatible with excellent clinical results [7]. Neither of these two heating technologies, especially hyperthermia that yielded better results, can be evaluated objectively concerning the analgesic effect, since the exact mechanism of action for pain relief or the changes caused by deep heating application on motor and sensory nerve conduction velocity remains still unclear [23]. Since the mechanism for healing of a damaged tissue is thought to be facilitated upon the transport of nourishing substances and removal of toxic waste from the same, we can speculate that the better therapeutic effect of hyperthermia is due to its capacity to evoke a more intense blood flow response in the tendon tissue. Blood flow response to hyperthermia, however, has been investigated by several authors [1,30–32]. Many studies have also proven that the increase of blood perfusion response is a function of temperature threshold [1,30]; to produce a significant rise in blood perfusion, at least 42 °C must be reached, while the therapeutic range for tissue is considered to lie approximately between 43 °C (the temperature whereby a vigorous blood flow response is obtained) and 45 °C (the approximate threshold temperature for the thermal destruction of tissues) [30,31]. Guy and Lehmann demonstrated also that the duration of tissue temperature elevation is another important factor in determining the extent of biological reaction, specifying that a minimal effective duration of elevation was 3 to 5 minutes, whereas complete reactions may be obtained with a 30 minutes application [16]. Both of these requirements, therapeutic temperature and duration, were achieved by the hyperthermia system at 434 MHz. On the other hand, many studies using local xenon 133 wash-out techniques, have demonstrated that continuous-wave ultrasound administered at a commonly prescribed dosage and duration, did not increase subcutaneous or muscle blood flow in human subjects [29,35]. It is our opinion that the question of ultrasound's ability to increase blood flow should not be concluded; it could be possible, however, to cause consistent changes in musculo-skeletal tissues blood flow, increasing intensity and duration of application but at the present this occurence is difficult to actuate in clinical practice without exceeding tolerable limits. Even with a small number of cases the early results of this study are encouraging, supporting the use of hyperthermia at 434 MHz in the treatment of chronic tendinopathies for its clinical effectiveness, lack of side effects and safety. In the near future further prospective well-designed controlled studies have to be done to confirm the therapeutic effect of this modality in a more extensive localization of tendon overuse conditions. The knowledge of the *in situ* real time blood perfusion rate increase during a hyperthermia session [22] as it is now possible to estimate with the more recent development of non invasive systems (i.e., laser-Doppler flowmetry at optics fibres) will be of paramount importance to better define the biological response of tendons to a heat dose.

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