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A controlled study on the effects of hyperthermia at 434 MHz and conventional ultrasound upon muscle injuries in sport

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Background. **Hyperthermia equipment using a 434 MHz applicator with water bolus elevate to therapeutic temperatures (from 41 to 45°C) delineated volumes of tissue target, down to a depth of 3 to 5 cm. The aim of our study was to evaluate the efficacy of hyperthermia in the treatment of muscle injuries, in comparison with a conventional modality like ultrasound.**

Methods. **A prospective randomised controlled design was used. Forty patients, 29 males and 11 females, with mean age of 26.2±3 ranging between 18 and 35 years affected by acute muscular injuries of different sites and severity participated this study. Twenty-one patients received hyperthermia (group A) and the remaining 19 (group B) ultrasound. Both groups received nine applications, three times per week with a duration of 30' for the group (A), and 15' for the group (B). All the patients underwent a clinical examination including a pain measurement and a ultrasound scanning before, at the end and after one month follow-up. An additional ultrasonography was made after the fourth session to compare the effect of each treatment on the initial course of haematoma resolution.**

Results. **Both groups had a significant decrease of the pain (p< 0.001). The hyperthermia group showed a significantly higher effect on VAS score and on haematoma resolution after two weeks of treatment.**

Conclusions. **Even with a limited number of cases our results show that the hyperthermia is a highly innovative, safe and reliable modality for the treatment of acute sport muscle injuries.**

KEY WORDS: Hyperthermia, induced - Muscle, skeletal, injuries - Muscle, skeletal, ultrasonography.

Heating with its different applied modalities, has been used for centuries in the treatment of several diseases, especially muscle and tendon injuries.[1] Conventionally, thermal agents available for biological tissue heating, fall within one of two main categories: superficial and deep heating agents. Superficial heating agents such as hot packs, wet-heat application, sand or mud bathing, paraffin wax, transfer heat to the body via conduction effect; deep heating agents such as radiofrequency (RF), (*i.e.* short wave therapy at 27.13 MHz), microwave (MW), (*i.e.* radartherapy at 2450 MHz) or ultrasound (US), (*i.e.* ultrasound-therapy at 1 to 3 MHz) diathermy, transfer electromagnetic or sound energy into biological tissue, that is converted into heat, thanks to the joule effect.

There is an heating class moreover, which operates with both the previously described categories; it combines a superficial system (air or water) with a deep heating source (RF, MW, US): in this last class the external cooling system (water-bolus) at variable temperature, allows to take away high levels of energy from superficial tissues, maintaining skin and fatty tissues under 42°C, while deep heating source is able to bring up the tissues to high temperatures down to a depth of about 5 cm.[2]

Comparative studies on the use of heat modalities on

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TABLE I.—*Anatomical site and degreee of injuries in both groups.*

Parameters	Anatomical sites				Grades of injury	
	Biceps femoris	Thight adductors	Quadriceps	M. gastrocnemious	2nd degree	3nd degree
Hyperthermia	13	2	3	3	18	3
Ultrasound	11	1	5	2	15	4

living tissues, such as muscles, tendon and joints, produced by superficial, deep heating and combined technologies have demonstrated the following points:

— perfusion is the overwhelming dominant physiologic factor regarding the thermal state of tissues;[3 4]

— the therapeutic temperatures for tissues are considered to lie approximately between 42°C (the temperature whereby a vigorous blood flow response (BFR) is evoked) and 45°C the critical temperature for thermal destruction of tissues;

— superficial heating agents don't reach therapeutic temperatures and increase temperature only at the skin level;[3 5]

— conventional deep heating agents reached therapeutic temperatures at depth of 1.8 cm but only on target volumes of limited dimensions (about 10-30 cm^3), with side effects such as overheating skin and fatty tissues and development of hot spots.[6] Experimental studies on time-temperature relationship quantified tissues damages produced by excessive hyperthermia in animals and humans.[7, 8] The approximate threshold for irreversible skin tissue damage is in fact 45°C (113°F) when the heat is applied for a sufficiently long period of time. For short periods of heat application, the skin can conversely tolerate higher temperatures without damage.[3] Hyperthermia equipments were recently introduced as a therapeutic modality for clinical use in physical medicine and sports traumatology; they were first applicated in oncology about three decades ago;[9 10] several investigations supported in fact their use in the treatment of malignant tumors, since the combination of hyperthermia with radiotherapy increases cytotoxic effect.[10] The results of these studies lend substantial support for attempting in clinical work to keep temperatures at or below 45°C for a maximum of 30 min. Today these technologies are considered as new heating combined system, since they use a superficial cooling system and a deep heating source operating with a microwave power generator at 434 MHz. The surface tissue cooling system allows a proper transfer of the heat into the tissues, with a very low dispersion of microwaves in the external environment, maintaining the surface temperature at controlled values.[2, 7] These hyperthermia systems are able to heat at temperatures between 41 and 45°C target volumes of approximately 100-200 cm^3.[2] Muscle injuries quite often involve the development of intramuscular haematomas and are one of the most common occurrence in athletic population.[11] During the resolution phase the purpose of any physical modality is to accelerate the healing process and the absorption rate of the haematoma. Because ultrasound therapy is often used to treat muscle injuries to accelerate the healing process and they are the most widely used deep heating modality in physical medicine,[12] we decided to assess the effectiveness of hyperthermia at 434 MHz in the treatment of muscle injuries in a randomised study using conventional ultrasound modality as a control. To date, there have been no clinical studies reported in the literature on the use of hyperthermia at 434 MHz in the treatment of muscle injuries in athletes.

Materials and methods

Between January 1998 and July 1999, a group of 40 athletes (29 males and 11 females), with a mean age of 26.2±3 (range 18 to 35), affected by acute muscle injuries with variable severity and site were recruited at the Physiotherapy Department of Institute of Sport's Sciences (Table I). A timespan of 72 hours between the injury and the beginning of treatment was stated as a selection criteria, in order to get over at least the acute phase of the injury, usually characterized by the presence of an intense inflammatory cell response. The exclusion criteria was a timespan longer than seven days between the injury and the beginning of treatment. The patients were informed that this was a randomized trial and they would be placed into one of the two treatments. However, none of them received any elucidation regarding the kind of modality or the application peculiarities, nor anyone had previous experience with ultrasound or hyperthermia treatment. After the approval of the patients to take part the study, one of the investigators contacted the principal investigator (AG), who assigned by chance (dice) the treatment program in which the athlete would participate. No one could change the randomization designated by the principal investigator. Group A, consisting of 21 subjects, with a mean age of 25.2±4 (range 19 to 33), was treated with hyperthermia at 434 MHz. Group B, consisting of 19 subjects, with a mean age of 27.3±5.6 (range 18 to 36), was treated with ultrasound. There was no significant difference between group A and B, as regard as to the age (p=0.181).

Subjective pain was measured with a 10 cm horizontal analogue scale (VAS: 0=no pain; 10=incredibly severe pain) during pain pressure and active resisted contraction manoeuvres of the muscle involved. The average of three ratings was taken as the best estimate of current pain on each subject. As a part of the pretreatment work-up an ultrasonography scanning by using a linear-array transducer (ESAOTE Biomedica AU4 idea) at 7.5 MHz was performed. An experienced musculo-skeletal radiologist (SD) interpreted all the images, to ensure a uniform evaluation. This clinical and instrumental protocol was used before at the end and one month after the end of treatment. Both groups received nine treatments three times a week 30 min long for group A and 15 min long for group B. Ten cases, 5 out of 21 in group A and 5 out of 19 in group B were selected to receive an additional ultrasonography at the midpoint of treatment (after the fourth session) in order to compare the effect of each treatment on the initial course of haematoma resolution. Linear measures of haematoma were made by ultrasonography calculating major length and width of blood collection in the sagittal and axial planes. For hyperthermia, treatment was administered with a 45-60 Watt power, according to size and depth of injury and thickness of fat tissue.

Pilot temperature was kept in a range of 37-40°C; the temperature of the water in the bolus was between 35 and 41°C. The threshold of thermal pain which corresponds to a skin temperature of 45°C, was never reached in any of the cases treated.

The sensor was always placed orthogonal to the electric field, being this a basic condition to minimize the electromagnetical coupling between the thermocouple and the applied electromagnetic field.

An intensity of 1,5 W/cm^2 was conversely used in the ultrasound treatment with continuous emission at a commonly dosage prescribed by the literature.[6, 13] A gel was underposed between the sound head transducer and the muscular treating area, in order to better conduct the diffusion of the mechanical sound waves into the tissues.

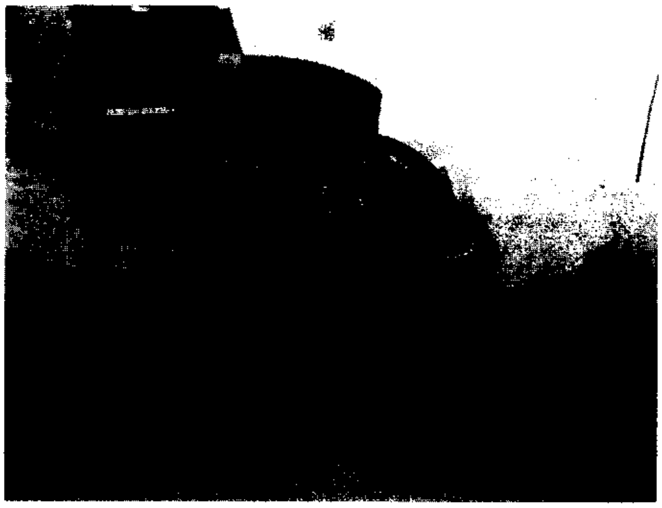

Fig. 1.—The hyperthermia system.

Statistical analysis

Raw data (means and standard deviations) were extracted from the outcomes of both groups. A pair "t"-test was applied to analyse the effectiveness of the two treatments . An unpaired "t"-test was used to determine which of the treatments had more effect on the subjective pain evaluation and objective measure of haematoma.

Deep heating instruments

Hyperthermia

An "ALBA Hyperthermia System" (RESTEK SRL ITALY) was used (Fig. 1). It was equipped with a 433.92 MHz microwaves 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

TABLE II.—*Results of VAS scores before and after treatment and % of improvement with each treatment.*

Parameters	Pain pression before	Pain pression after	% improvement	Pain active contraction before	Pai active contraction after	% improvement
Hyperthermia (mean±SD)	5.5±1.9	1.2±0.7	77	4.6±2.3	1.0±0.9	78
Ultrasound (mean±SD)	5.7±2.1	3.3±0.3	42	5.4±2.0	3.2±1.3	41
p	0.001			0.01		

TABLE III.—*Results of haematomas measurements by ultrasonography after the fourth session.*

Parameters	Hyperthermia (cm)		Ultrasound (cm)	
Mean±SD	3.38±0.31	2.16±0.27	3.32±0.32	2.78±0.19
p<	0.0008		0.0013	

transfer while preventing the overheating of superficial tissues near to the radiant source; an 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.

Security system is strictly developed under specifications given by the EEC 93/42 rules for the class IIB apparatuses. The equipment ceases delivering electromagnetic energy in case of temperature sensor breaking, malfunction of the control power generator, damage at the computer control hardware or excessive exposure of radiofrequency on the environment over 35%.

Ultrasound

A Level 730 device (Mettler Electronics Corporation USA) was used. It was equipped with an emission probe of 1 MHz frequency, a soundhead with an effective radiating area (ERA) of 10 cm^2 and a maximum output power of 22 W.

Results

Effectiveness of each treatment

In both groups (A and B), the "t"-test showed a statistically significant reduction of the VAS scores as regard as to pain pressure (ultrasound: T=10.5, p=0.0001; hyperthermia: T=16.1 p=0.0001), (Table II) and pain on active contraction (ultrasound: T=10.4 p= 0.0001; hyperthermia: T=9.8 p=0.0001), (Table II). A significant improvement was also detected on the haematoma resolution objectively measured after the fourth session (ultrasound: T= 79 p=0.0013; hyperthermia: T=9.2 p= 0.0008), (Table III).

Comparison between ultrasound and hyperthermia

The results showed a significant difference between the two treatments. Hyperthermia had a significantly higher effect on the reduction of the VAS scores as regard as to pain pressure (T=8.15, p=0.0001) pain on active contraction (T=6.11, p=0.0001) and haematoma resolution (T=41, p= 0.0035).

Discussion and conclusions

Broad interest, as it has been already produced in oncology, is now being generated by the use of hyperthermia equipments at 434 MHz in physical medicine and rehabilitation with protocols similar to those utilized for the treatment of radio-resistant malignant tumors.[9 10 14] Hyperthermia devices at 434 MHz are able to characterize the volume and the maximum depth of the heated tissue, to control real time the reached temperature at surface or at a given depth measured with special thermometers located on the skin in the point of maximum heating with an absolute accuracy of 0.2°C in the range of 30 to 50°C.[2] They also allow to know the temperature of the superficial water cooling system and the amount of dispersed and non-irradiated energy levels with no chance of overheating or burning the overlying superficial tissue, evenience that frequently occurs using the conventional diathermy.[15] The use of bi-dimensional simulation softwares developed according to the "bioheat equation" carefully simulated thermal dose with regard to blood perfusion behaviour of different biological tissues (skin, fat muscle, and tendon), to the size and depth of the lesion, in order to make also the less skill operator confident about the parameters (pilot temperature, water bolus temperature and power) to be used for a specific tissue heating.[16] The safety element is besides guaranteed with these machines, even for a pain threshold overcoming referred by the patients as a sharp aching pain, where it is only necessary to lower the power generator to a non pain level to continue the application in a safe way. Muscle injuries are among the most common traumas in sports medicine; their incidence varying from 10 to 55% of all injuries sustained in sport events.[17] Although they are generally labelled as a minor trauma, sometimes of doubtful diagnosis, they can account for significant disability because of their frequency as well as their symptoms, not only in high level athletes but also in amateurs.[11] It must be underlined that even if a variety of physical modalities (like ultrasound, lasers and different forms of electrical currents) have been recommended as a treatment by several authors, no clinical evidence exist of their effectiveness due to a lack of prospective randomized controlled studies.[18-21] Using an unsuitable treatment, it is possible to cause adverse complications which can remarkably prolong the recovery phases of the injuried athlete. Diathermy, superficial or deep tissue heating, is based up to now, on the subjective empirical experience of the operators, largely ignoring the fact that experimental and clinical studies have demonstrated, more than 20 years ago either the limitations of some of the heating modalities, or the required mechanisms to produce a significant increase of blood perfusion.[22-24] The ameliorating effects of heating tissues in fact, have long been associated with the augmentation of blood flow (BF); the mechanism that more influence the healing process of a damaged tissue is thought by several authors, to be highly dependent upon the transport of blood nurturing substances and removal of toxic waste products.[25-27] Muscle injuries quite often involve the development of intramuscular haematomas so, during the resolution phase the main purpose of the physical therapy is to accelerate the absorption rate of haematoma to speed the regenerative processes.[28] Fenn produced haematomas in rabbit ears by subcutaneous injection of blood, heating the site of haematoma with short wave diathermy at 27.12 MHz.[29] The results, quantified by photographing the area of discoloration and measuring its size and color changes, showed a statistically significant increase in the absorption rate with treatment. Lehmann first quantified the resolution rate of haematomas, creating bilateral experimental haematomas in six pigs by intramuscular injection of blood labelled with CR51 radioisotope;[25] Microwave at 915 MHz were applied to a single lesion in each animal; a contact method was used and the second lesion acted as a control. The results demonstrated that tissue temperature at the treated site was in the therapeutic range between 42 and 45°C. A decay curve for the radioisotope showed that the time to the half life value was significantly shorter for the treated site. Due to ethical problems and since all participants the study were competitive athletes with the urgent need to come back to specific sport's activity, we did not voluntarily include a control group with sham treatment, but we utilized two treatments, which could be clinically effective. We used ultrasound equipment at a frequency of 1 MHz with an intensity of 1.5 W/cm^2 for a duration of 15 min, instead of the commonly 5 to 10 min prescribed by literature, to achieve better thermal benefit allowing more energy to be available for absorption and elevation of muscular tissues temperature. Our controlled study between hyperthermia at 434 MHz and conventional ultrasound in the treatment of muscle injuries located at lower extremities, provided in both groups a statistically significant reduction of pain during muscle pressure and active contraction manoeuvres, at a visual analogue scale measurement (VAS). Even if this kind of pain assessment gives subjective information, its reliability has been very well documented.[30 31] We didn't consider to collect anymore objective data like a strenght or a ROM evaluation because it would be strongly influenced by the symptoms. This study showed also a statistically significant improvement of haematoma resolution after two weeks of treatment. Hyperthermia however, resulted significantly more effective on VAS scores and absorption rate of haematoma as respect as to ultrasound (Fig. 2). Therapeutic ultrasound is widely recommended and also used in the treatment of muscle injury, although no clinical evidence exists of its effectiveness.[18 19] The use of ultrasound has been claimed to have a beneficial effect in the initial stage of regeneration since the micromassage provided by ultrasound waves serves as a means of pain relief. In a study on animals with experimental induced contusion injury Rantanen *et al.* (1995, unpublished data) didn't draw definitive conclusions on the effect of ultrasound on the final outcome of myoregeneration process. The poor effect of ultrasound in our study respect to haematoma resolution could be due to the fact that administration of continuous wave ultra-

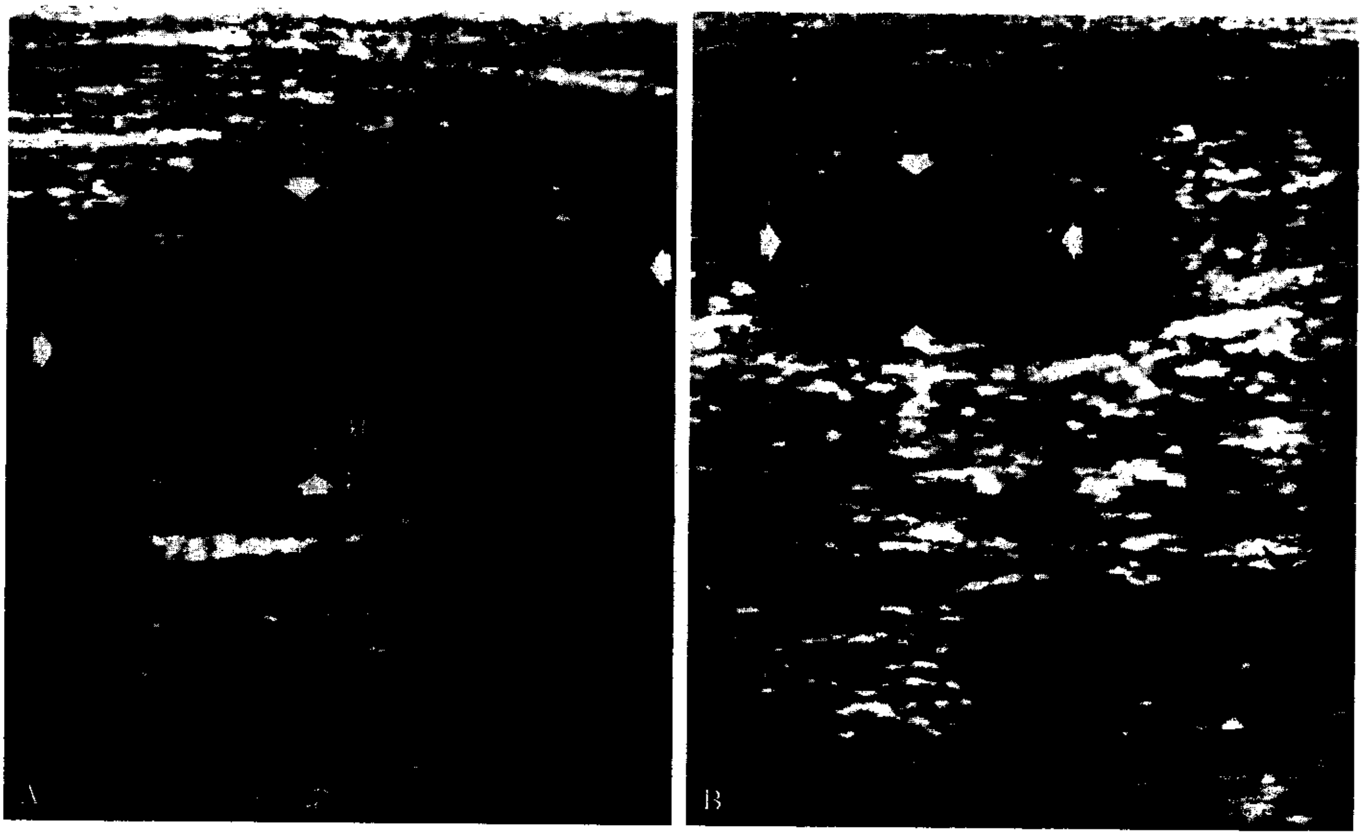

Fig. 2.—III degree medial gastocnemious sprain, treated with hyperthermia. A) Before treatment. B) After the fourth session.

sound at clinical dosage (1,5 w/m^2) and duration (15 min) had a limited effect on local skeletal muscle blood flow.[6, 32-34] On the other hand there is no scientific evidence that doubling the application time of daily dosage or increasing the frequency these results will be achieved. It is our opinion that muscle hyperemia is probably not the primary mechanism of action of ultrasound. Another important result of the study was the lack of any re-occurences and side effects in the group treated with hyperthermia neither during nor at one month follow-up; even if it is no possible to certainly establish a cause effect relationship with the modality used, three re-occurrences and one calcification in a second degree hamstring strain, occurred in the ultrasound group.

One of the limitations of our study was, not to have been able to evaluate both treatments in relation to cellular responses to strain injury.[17, 35] *In situ* muscle tissue biopsies will permit in a short time to better comprehend the biological cell response to a heat dose during the rigeneration process. Even with a small number of cases and the inevitable pathological diversity of muscle lesions, our preliminary study provided evidence that hyperthermia at 434 MHz is highly innovative and safe technique. It is equipped with a sophisticated non invasive temperature control system, that thanks to the use of microthermometers placed on the surface above the area to be treated estimated in real time the effective temperature reached, producing an homogeneous increase of temperature in the target volumes down to a depth of several centimeters[2] decreasing any risk of overheating or burning the superficial tissues.

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