*in co-operation with Catanzaro University*

# Cryoultrasound: our experience

LONGO[1], A. AMMENDOLIA[2], A.M. COLAO[1], L. FRATTO[1], R. FRATTO[1], S. VILLELLA[1], M. IOCCO[1]

Cryoultrasound is an apparatus which is based on the synergy between the two therapeutic techniques known as cryotherapy and ultrasound therapy. These two techniques boost each other reciprocally, sidestepping eventual complications due to the heat effect of the ultrasounds in acute and sub-acute traumas. The use of Cryoultrasound eases the healing process with a quicker recovery due to the interruption of the pain-spasm-inactivity cycle. This device is indicated in the treatment of people who have suffered a recent trauma or in the presence of an acute or sub-acute in inflammation.

**Materials and methods**

From September 2005 to January 2006, 21 patients were enrolled in our study, their average age was 42.57+12.18 years (range 24-61 years). Our inclusion criteria was the following: muscle contusion without blood effusion, muscle strain without blood effusion, 1st and 2nd degree muscle sprain, peritendinitis, peritendinitis with tendinosis, insertion tendinopathies e fascitis. We treated 3 females and 18 males suffering from the pathologies listed in Figure 1. The diagnosis was effected through clinical examination and confirmed with ultrasound scan on all patients before and after treatment.

The criteria adopted for exclusion was: having undergone previous physiotherapy treatment within six months of the beginning of the treatment with Cryoultrasound and, in order to avoid confusing factors during the reading of the ultrasound scan, the presence of concomitant pathologies which could influence the reliability of the instrumental readings. Each patient signed an informed consensus form before entering the questionnaire and undergoing clinical assessment. The clinical history of all patients was taken. The questionnaire collects three different types of information. The first part focuses on personal data such as: marital status, level of education, job, sport practiced and performance levels reached.

The second part, regarding the period preceding the treatment and assessing the disability, investigates the perception of the patient's state of health, pain and to what degree daily activities are effected, the eventual intake of drugs prescribed in the therapy. Finally, the last section, compiled at the end of the Cryoultrasound treatment cycle, asks the patient how he/she came to know about this therapy, what degree of inconvenience is perceived during the sessions and what perception the patient has of the beneficial effects obtained.

Before the doctor in charge compiled the clinical assessment forms, the patient gave personal impressions of the pain perceived on the basis of the visual analogic scale (VAS) set on levels ranging from 0 to 10 intensity. The clinical assessment investigated the times of onset of pain with respect to activity, pain on digital pressure and in movements against resistance, the daily activities possible, the limitation in articulation range and muscle strength. Eventual additional instrumental examinations were attached.

The dietetics operational unit of our institute effected a baseline assessment of the physical characteristics of the patient to modify, if necessary, the duration of the sessions on the basis of the thickness of the adipose tissue of the patient.

*1Cattedra di Medicina Fisica e Riabilitazione,*
*Policlinico "Mater Domini", Università degli Studi di Catanzaro;*
*2Clinica Ortopedica, Policlinico "Mater Domini",*

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Subsequently every patient underwent a cycle of 10 applications with Cryoultrasound. Every single session, scheduled on a daily basis, was carried out using an apparatus with the characteristics listed in Table I.
The protocols followed were distinct and varied according to the pathologies treated:
Muscle contusions and sprains without blood effusion:
– n° 10 daily sessions (5 sessions a week)
– applications lasting: 20 min
– continuous emission
– direct contact with mobile head technique
– power: 2°C /0,6-0,8 W/cm2
– 2. 1st and 2nd degree muscle sprain:
Phase 1 (immediately after the trauma)
– n° 5 daily sessions (5 sessions a week)

1. Tendinopathy of the rotator cap(18%)
2. Tendinopathy of Achilles heel (18%)
3. Recto-adductor syndrome (14%)
4. Lesion of the median twin (10%)
5. Lesion of the anterior recto and the vastus medialis (10%)
6. Epicondylitis (10%)
7. Plantar fascitis (10%)
8. Tendinopathy of the fibula muscle (5%)
9. Tendinopathy of the finger extensor muscles (5%)

Figure 1. – Treated pathologies

– applications lasting: 20 min
– modulated emission
– direct contact with fixed head technique
– power: 2°C /0,8-1 W/cm2
Phase 2
– n° 5 daily sessions (5 sessions a weeks)
– application lasting: 20 min
– continuous emission
– direct contact with mobile head technique
– power: -2°C /1,6-1,8 W/cm2 (in case of deep set or particularly thick muscles a power of between 2 and2,2 W/cm2 and a temperature of –2°C was applied)
– 3. Insertional tendinopathies, peritendinitis, tendinosis, fascitis:
– n° 10 daily sessions (5 sessions a weeks)
– application lasting: 20 min
– continuous emission
– direct contact with mobile head technique
– power: -2,-4°C /2,0-2,4 W/cm2

The probe was positioned on the injured part which was indicated by the patient as being the more painful. The descriptive statistics was used to describe the population characteristics. The comparison of readings in the VAS scale was conducted with the aid of the t-test for matching data. Readings of p<0,05nbwere considered to be significant. The data was analysed with SPSS software.

**Results**

Table II shows the characteristics of the baseline sampled patients.

71% of patients was married (29% were single) and 57% had a secondary level education.

86% had a sedentary job and only 29% practiced some kind of sport on a weekly basis at non professional level.

71% considered themselves in good health and the present pathology was responsible for a partial limitation in physical activities (e.g. running). In 57% of cases there was no limitation in daily activities.

Pain was perceived as moderate in 43% of cases and intense in the remaining 57%, the same percentage for which drugs (FANS), used prior to the Cryoultrasuonotherapy, procured a moderate relief.

86% of patients had learned of the treatment after having been seen by a specialist and 71% of these did not perceive the treatment as unpleasant or painful, and was reasonably satisfied with the results.

86% said they would repeat the treatment if necessary. The percentage of patients who complained of pain on digital pressure or palpation on the interested part dropped from 71% to 43% from the pre-treatment phase to after the tenth session of treatment.

Table III highlights the average scores, the standard deviation and the statistical comparison of the readings in the VAS scale in the pre-treatment phase (T0), after the fifth session (T1) and after the tenth session (T2).

The VAS scale showed a reduction in the overall average reading at both the T1 and T2 stage (variation % T0-T1 39,62 and T0-T2 64,15). This represents a pain reduction perceived at the end of the treatment with respect to the reading calculated on the baseline. In both cases this variation resulted statistically significant.

**Discussion**

Therapeutic treatment with ultrasound is one of the most widely and frequently adopted therapies with physical agents[1,2]. But in spite of the over 60 years of clinical applications[3], the efficacy of ultrasound in pain control treatment[4], of muscoloskeletric lesions and lesions of the soft tissues remains debateable.

In a systematic review of random and controlled trials in which ultrasound was used for the treatment of the above pathologies, only a mild evidence of its therapeutic efficacy compared to the placebo treatment was highlighted[5]. Mild evidence which, in the treatment of muscoloskeletric lesions, is confirmed also in the review conducted by Van Der Windt[6], in spite of the fact that 13 random and placebo-case controlled studies of the 38 included, provided with adequate methodology, did not support the existence of clinically or statistically significant differences in favour of ultrasound therapy.

In spite of this, a significant pain reduction emerged from our treatment protocol which resulted significant in the statistical analysis.

In this study, however, the use of Cryoultrasound enabled the systematic combination of ultrasound therapy with cryotherpapy to reduce the effects of the heat induced by the ultrasound. In fact, the continuous mode of the application in a single session, not associated with cryotherapy, caused an increase in temperature of the subcutaneous tissues of 0,8°C and an increase in the nerve conduction speed from 3,08 to 3,75 m/sec after 5 minutes of application[7]. Furthermore, also the variations in the latency of nerve conduction in healthy patients after ultrasound application appears to be correlated to the change of temperature induced by the thermal effects of the ultrasound and not by the non-thermal or mechanical effects of the same[8].

But it is necessary to specify how these variations in nervous conduction are not correlated in a linear fashion with the changes in the skin temperature, although the effect of the temperature are more evident in the lower ranger of the same. Particular attention is focused on the fact that the conduction speed of the sensitive fibres, maximum and minimum in the temperature range between 19-38°C, increases in a non linear fashion with respect to the increase in skin temperature.

Table I. – Technical characteristics of the apparatus.

| | |
|---|---|
| Power supply | 220 Volt - 50 Hz |
| Watts | 650 Watt |
| Max ultrasound output power | 3 Watt/cm2 |
| Frequency | 1 MHz ± 5% |
| Type of emission | continued and intermittent / 50-100 Hz |
| Electronic timer | from 0 to 30 minutes |
| Transducer | piezoelectric ceramic |
| Visualization | through digital display |
| Cryoterapia | adjustable up to -5° C |

Table II. – Characteristics of the group.

| | |
|---|---|
| Age (average + DS) | 42.57 + 12.18 |
| Men/Women | 18/3 |
| Height (average + DS) | 171.7 + 9.275 |
| Weight (average + DS) | 76.14 + 10.97 |
| Fat % (average + DS) | 26,61 + 4.75 |

Table III. VAS scale: descriptive analysis and statistical comparison

| | |
|---|---|
| VAS T0 (average + DS) | VAS T1 (average + DS) |
| 7.571 + 0.5071 | 4.571 + 2.039* |
| VAS T0 (average + DS) | VAS T2 (average + DS) |
| 7.571 + 0.5071 | 2.714 + 1.793* |

* p<0,05

Similarly, the distal motor latencies increase not linearly with the reduction of the skin temperature, and with respect to the latter, the extent, both with regard to the sensitività and motor aspects, does not show any significant relation[9].

In further evidence of the functionality of this association, one can observe how the perception of the strength signals required for the discrimination of weight does not appear to e compromised by the local muscle cooling, thus constituting an additional note for the relative safety of cryotherapy and its effect on proprioceptive capacity[10]. Also because the

use of temperature reduction does not alter the neuromuscular control of the injured tissue[11].

And there is also no difference in the use of different cryotherapy conductor methods. In fact, fifteen minutes after removing the ice or any kind of cold compress,, there is no evidence of significant variations at an average skin temperature level, and no reduction of temperature was observed 1cm from the part in which the cooling agent was applied[12].

It should be stressed, instead, how subcutaneous tissue temperature is directly correlated to the intensity of the ultrasound applied. Until an intensity of 1,5 W/cm2 is reached, there are no thermal effects or the cooling effect of the gel is denied. To produce significant increase in the temperature of the subcutaneous tissues you need a 5 minute application, and the interruption of this linear relation occurs at an intensity of 2,5 W/cm2.

In order to produce a cooling effect the cryotherapy treatment time varies form patient to patient depending on the thickness of the subcutaneous adipose tissue. The analysis of the variance reveals that the average time needed to reach an intramuscular temperature reduction of 7°C increases as the thickness of the adipose tissue increases, the average + the standard deviation of the cooling time is the following: 31-40 mm (58,6+11,7 min), 21-30 mm (37,8+9,6 min), 11- 20 mm (23,3+6,7 min) e 0-10 mm (8,0+3,4 min) 14.

It was not necessary in our treatments to recur to variations in the application times of the cryoultrasound therapy with respect to the standardized protocols due to the presence of a percentage of subcutaneous adipose tissue, in accordance with the literature, such a sto be included in the times adopted.

The utility of the therapeutic association provided by Cryoultrasound in reducing the thermal effects of ultrasound therapy, is also confirmed in a study by Draper et al[15]. A 23-gauge hypodermic needle was inserted, under anaesthetic, at a depth of 5cm into the medial portion of the sural tricept on 16 volunteers.

Each volunteer was given a 10 min ultrasound therapy in continuous mode at a power of 1.5 W/cm2, eight of these patients were given a 5 minute cryotherapy pre-treatment. A significant difference was observed between the two groups. The ultrasound therapy not associated with cryotherapy determines an average increase in muscle temperature of 4.0 +/- 0,83°C, whereas te treatment with ultrasound preceded by cryotherapy increases tissue temperature of only 1.8 +/- 1,0°C with respect tp the baseline. One can therefore conclude that the ultrasound-cryotherapy synergy is associated with reduced thermal effects.

In a comparative study conducted at the O.U. of Physical and Rehabilitation Medicine of the University of Parma[1], Cryoultrasoundtherapy was compared with CO2 laser therapy and with TECAR therapy the treatment of tendinopathies. A significant difference was observed with regards to CO2 laser therapy in favour of Cryoultrasoundtherapy and an improved average range of efficacy with respect to TECAR therapy. It can therefore be confirmed that Cryoultrasound is useful in the treatreatment of tendinopathies.

**Conclusions**

Treatment with Cryoultrasound is currently under study, consequently further more significant data will be available as the research continues.

In any case, notwithstanding the limitations due to the very limited sample number, we can conclude that the results obtained to date are encouraging for a satisfactory response to treatment.

**Summary**

Object of this study was the evaluation of the therapeutic efficacy in the use of ultrasound therapy associated with cryotherapy in the treatment of muscle and tendon injuries. For this purpose, we used Cryoultrasound therapy, an apparatus which is based on the synergy of the two above mentioned therapeutic techniques. From September 2005 to January 2006, 21 patients were enrolled in the study. Every patient underwent a cycle of 10 applications, at the end of which we observed a statistically significant variation in the scores calculated in the VAS scale. The treatment with Cryoultrasound is currently under study, consequently more relevant data will be available with the progress of the study In any case, notwithstanding the limitations due to the very limited sample number, we can conclude that the results obtained to date are encouraging for a satisfactory response to treatment

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