TREATING CHRONIC LUMBAGO WITH MLS THERAPY.

A CONTROLLED TRIAL.

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This trial assessed the effectiveness of MLS Therapy in treating chronic lumbago. 30 patients affected with the illness were subjected to monotherapy with MLS Therapy, monitoring painful symptoms through the use of the Visual Analogue Scale (VAS). The results were compared with the progress of symptoms recorded in a homogeneous control group as regards numbers and composition. After 10 treatment sessions, a significant reduction in painful symptoms was observed and a fair amount of mobility was recovered. The above results confirm the effectiveness of MLS Therapy in treating chronic lumbago of a mechanical nature.

Introduction

Lumbar pain is a symptom of variable etiology that is very widespread amongst the adult population, especially young adults in industrialized countries. Numerous epidemiological studies have been carried out over recent years, with varied findings as regards the incidence and social impact of this disease. This lack of accurate data is linked to the different sources of information, the very definition of lumbar pain, the various forms of behavior of sufferers depending on insurance systems and, finally, the different treatments used in different countries. In order to get a clear picture of the capacity of this phenomenon, it will be useful to provide some information on the prevalence of the disease, especially in the work environment, and its consequent economic impact. In Great Britain, for example, 46% of a random sample of the general population claims to have suffered from lumbago at least once in their lives. Also in Great Britain, there were 15 million medical visits for lumbago in 1993, leading to 1.5 million spinal X-rays, one million patients treated with rehabilitative physiotherapy, 100,000 hospital admissions, 30,000 day-hospital days and 24,000 surgical operations. Lumbago costs the country an estimated 520 million Euro/year.

The disease also has extremely high social costs. In fact, the statistics drawn up by the British social security institute indicate 81 million

paid sick days due to backache in 1991-92, with an estimated increase to 106 million days per year by 2002-2003 (Waddell G, 1996; Andersson GB, 1999).

Laser therapy plays an extremely important role in the field of physiotherapy used on a daily basis in outpatient departments, since the biological effects of the Laser light provide an analgesic, anti-inflammatory and biostimulating effect (England S et al., 1989; Ernst E et al., 1993; Gam A et al., 1993; Tuner J and Hode L, 2002). The difficulty in conducting random controlled trials (RCTs) (Beckermann et al., 1992) on such a widely prescribed therapy, leads to a lack of coherent data in literature, also because of the absence of indications on the physical parameters used (wavelength, frequency, dosage, application method, treatment duration) (Brosseau L. et al, 2000; Vasseljien O. et al, 1992).
However, it was found that modulating the wave shape plays a fundamental role in patient response to the therapy, and that certain types of Laser pulses are able to provide greater therapeutic effects (Corti L et al., 2003; Fortuna D et al., 2002). This trial was planned in order to assess the effectiveness of Laser therapy using a specific Laser pulse, known as the MLS pulse (Multiwave Locked System), obtained through the combination and synchronization of two different Laser emissions, on a homogeneous sample of subjects affected with chronic lumbago of a mechanical nature.

Population and Methodology

30 subjects with an average age of 39.63 were involved in the trial (DS 3.54 years, range 29-47), including 13 men and 17 women.
In order to be admitted to the study, patients had to have been suffering from the pain for more than three weeks and the pain had to be due to lumbago of a mechanical nature.

Clinical protocol	
N° sessions	10
Individual session duration	2 min
Treatment parameters	
Pulse repetition frequency	700 Hz
Dose supplied	2.02 J/cm^2

Table 1: Clinical protocol and treatment parameters

During the initial check-up, all the patients were subjected to a cognitive investigation of the pain symptoms using the "Visual Analogue Scale" (VAS), and therefore to a specific objective evaluation.
All the patients started exclusive physiotherapy immediately using MLS therapy supplied by the MIX5 (ASA, Arcugnano, Italy) device, able to supply the MLS pulse. There were ten consecutive sessions (table 1), each lasting 2 minutes, using a pulse repetition frequency of 700 Hz, a total quantity of energy supplied per session of 39.67 J and an energy dose of 2.02 J/cm^2. The multidiode applicator, with a 5 cm diameter, is positioned on the lower back, focusing on the multifidi muscles, since these are the main muscles involved in chronic mechanical lumbago.

At the end of treatment, all the subjects were re-assessed using the same methods, after an average space of 15 days (DS 1; range 14-16) from the initial assessment. The pain was also assessed using a binary ordinal scale expressed in: improvement of the symptoms (positive result) and stasis or worsening of the symptoms (negative result). A second group of 30 subjects, matching the first group as regards age, sex and pathology, was also recruited. The subjects in this second group were given traditional therapy around 15 days after the initial assessment. Immediately before starting treatment, they were subjected to another check-up using the same methods. The control group was necessary in order to assess any modifications linked to the natural course of the disease, and the reproducibility of the data, or rather a methodological error; because of this, the VAS scale was administered to each subject twice within the space of an hour during the check-up.
In order to assess the progress of the painful symptoms of the subjects treated, the data collected by the VAS scale was monitored on a daily basis, before each session.
All 30 subjects in the study group were forbidden to take any other

form of treatment, such as drugs, physio/kinesitherapy, etc.

The results were statistically analysed using ANOVA tests for measurements, repeated before and after treatment (pre and post), of the variable in question (VAS) with one and two group factors: the group and the outcome. Average differences of $p < 0.05$ were also considered significant.

Results

In the control group, the variance analysis (ANOVA) did not find any significant differences in the average VAS values during the two evaluations carried out within a short space of time. In fact, the values were 6.88 for the second evaluation and 7.02 during the first ($p = 0.51$). Consequently, the average differences between the two measurements were not significantly above 0, thereby excluding the existence of a systematic error in the measurement technique.
The extent of agreement of the measurement pairs was expressed using the coefficient of repeatability, or rather 2DS of the measurement pairs, which was equivalent to 0.41 (figure 1).
In fact, rather than a causal error in the measurement method, finding a difference in absolute value above the repeatability coefficient represented a real modification in the variable measured.

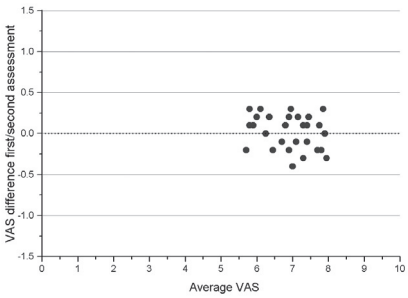

Figure 1: Control group. Difference between VAS score at first and second assessment.

In the control group, no significant different in the average VAS values was found between the evaluation carried out immediately before the start of treatment and the evaluation carried out initially, around 15 days earlier: 6.79 v. 7.02 ($p = 0.43$); this means that the course of the disease itself did not have any effect on the painful symptoms. As regards the pain reported at the end of treatment by the study group, comprising a total of 30 subjects, 25 (83.3%) reported a "positive result" expressed as an improvement in the

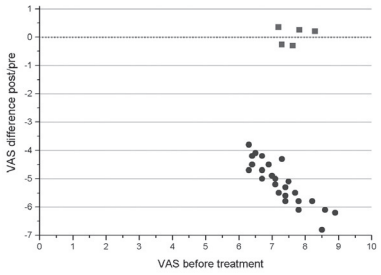

Fig. 2: Difference between post-treatment VAS and pre-treatment VAS on the basis of the pre-treatment VAS score.

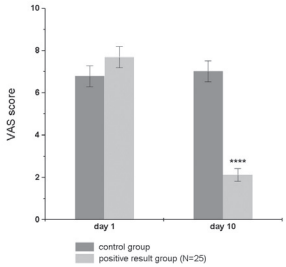

Fig. 3: Average VAS scores relative to the control group and the group treated with MLS Therapy (positive result subgroup, No. 25) measured on day 1 and day 15.

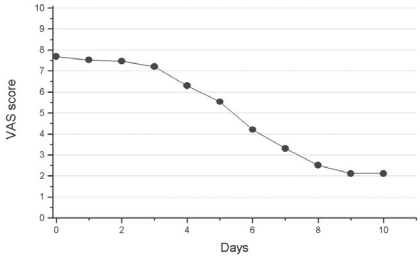

Fig. 4: Positive result subgroup: daily progress of average VAS score.

symptoms, while 5 (16.7%) reported a "negative result".

The results relative to each subgroup are illustrated in the diagram in figure 2, where the circles represent the VAS differences of the " positive result" subgroup and the squares the differences of the "negative result" subgroup. In particular, 3 of the latter subjects recorded a stasis of symptoms and 2 stated that the symptoms had got worse.
In the "negative result" subgroup, the post treatment values did not change significantly ($p = 0.62$) with respect to before the treatment, respectively equalling 7.71 and 7.46; none of the individual variations had an absolute value above the coefficient of repeatability.
In the "positive result" subgroup, the average post treatment values fell significantly ($P<0.0001$) with respect to before the treatment, falling from 7.69 to 2.12 (figure 3); the individual values diminished in all 25 subjects, in keeping with or more than the coefficient of repeatability.

The daily progress of the painful symptoms (expressed as average VAS score in the "positive result" subgroup) during treatment with MLS Therapy is represented in figure 4, where it can be seen that the most significant changes are concentrated in the period between the fourth and eighth day.

Conclusions

MLS therapy is particularly effective in treating chronic lumbago of a mechanical type, ensuring a high percentage of success (83.3% of patients treated) in the reduction of painful symptoms, even in consideration of the fact that this treatment was applied as a monotherapy. The reduction in painful symptoms was extremely

significant and was obtained with a reduced number of applications, each of which was particularly brief.

It can therefore be surmised that MLS Laser therapy is able to offer a good chance of reducing or resolving the painful symptoms of chronic lumbago using a “non-operator dependent” method able to reproduce the same effect.

Bibliography

- Andersson GB.
  Epidemiological features of chronic low-back pain.
  Lancet 1999, 354(9178):581-5
- Beckerman H., de Bie R., Bouter L., De Cuyper H., Oostendorp R.
  The efficacy of Laser therapy for Musculoskeletal and skin disorders: a criteria-based meta-analysis of randomized clinical trials.
  Phys. Ther. 1992 Jul; 72 (7): 483-91
- Brosseau L., Welch V., Wells G., de Bie R., Gam A., Harman K., Morin M., Shea B., Tugwell P.
  Low level Laser therapy (classes I, II and III) in the treatment of rheumatoid arthritis.
  Cochrane Database Syst. Rev. 2000; 2: CD002049
- Corti L., Maccari M., Zaghetto L., Pagnutti S., Rosa E.
  Laser treatment of cervical distortion.
  Laser and Technology 2003; 13 (1-2), 27-30
- England S., Farrell A., Coppock J., Struthers G., Bacon P.
  Low power Laser therapy of shoulder tendonitis.
  Scand. J. of Rheumatol. 1989; 18 (6): 427-33
- Ernst E., Fialka V.
  Low-dose Laser therapy: critical analysis of clinical effect.
  Schweiz Med. Wochenschr 1993 May 8; 123 (18): 949-54
- Fortuna D., Zati A., Mondardini P., Ronconi L., Paolini C., Bilotta T.W., Masotti L.
  Low Level Laser Therapy (LLLT) ed efficacia clinica.
  Medicina dello sport. 2002; 55, 1-8
- Gam A., Thorsen H., Lonnberg F.
  The effect of low-level Laser therapy on Musculoskeletal pain: a meta-analysis.
  Pain 1993 Jan; 52 (1): 63-6

- Mokhtar B., Baxter G., Walsh D., Bell A., Allen J.
  Double-blind, placebo-controlled investigation of the effect of combined phototherapy/low intensity Laser therapy upon experimental ischaemic pain in humans.
  Lasers Surg. Med. 1995; 17 (1): 74-81
- Tuner J. and Hode L.
  Laser Therapy – Clinical Practice and Scientific Background.
  Prima Books Ed. 2002
- Vasseljen O., Hoeg N., Kjeldstadt B., Johnsson A., Larsen S.
  Low level Laser versus placebo in the treatment of tennis elbow.
  Scand. J. of Rehabil. Med. 1992; 24 (1): 37-42
- Waddell G. (1996)
  Low back pain: A twentieth century health care enigma.
  Spine 21:2820-2825