ACUTE CERVICAL PAIN IS RELIEVED WITH GALLIUM ARSENIDE (GaAs) LASER RADIATION. A DOUBLE-BLIND PRELIMINARY STUDY

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Seventy-one patients with acute cervical pain were randomized in two groups. Group A, 37 patients was irradiated with a pulsed GaAs diode laser, 904 nm, pulse width 200 nsec, pulse frequency 10,000 Hz, peak power of 20 W, average power 40 mW, spot size 150 μm^2 in area (incident power density of approximately 26 W/cm²), and an angle of divergence of 6°. The laser was applied in the point technique with a dose of 4 J/cm² per point in the area of pain. Group B, 34 patients, was treated with sham irradiation with a deactivated laser system. Neither the patients nor the operator knew which group each patient was randomly assigned to. The use of analgesic drugs and physical therapy was excluded in both groups. Pain was evaluated through a linear colour scale. Laser treatment was considered effective when pain relief was more than 60%. The treatment was effective in 94.59% of patients in group A, and 38.24% of group B ($P < 0.0019$). The pain was relieved completely in 67.56% of patients in group A, and in 17.65% in group B. In patients in whom the response to the treatment was effective, the pain returned in the six months following treatment in 14.28% of group A but in 58.33% of group B ($P < 0.005$). No side effects were observed. These results suggest that GaAs laser radiation is an efficient and safe treatment for patients with acute cervical pain. Six years have passed since we incorporated the GaAs laser into our therapeutic arsenal and up to date we have irradiated more than two thousand patients with different kinds of pain and pain sites. The aim of this work is to evaluate the real therapeutic effect versus the placebo effect of laser therapy in patients with acute cervical pain in both the immediate effect and the possible latency of the pain relief with LLLT.

Key words: cervical pain, gallium arsenide laser, low level laser therapy, osteoarticular pain

Introduction

Acute cervical pain is a cause of frequent consultation in the authors' institute and elsewhere. Most of the affected patients suffer from osteoarthritis, alteration of the cervical axis or contracture of the paravertebral muscles, and usually they present with a combination of at least two of these situations.⁽¹⁾ The treatment of the pain requires the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and physical therapy. Usually the pain is relieved within 3 to 15 days of treatment, and a high percentage of patients note a recurrence of the pain

during the six months following the treatment.⁽²⁾ This is not a completely harmless treatment, because the NSAIDs can cause undesirable secondary effects, chiefly in the areas of the stomach, haematology, kidneys and skin.^(3,4)

Many reports say that irradiation with low level laser therapy is capable of relieving acute and chronic osteoarticular pain without causing side effects.⁽⁵⁻⁹⁾ However, a critical review of the literature shows a noticeable absence of well designed works that enable clear differentiation of any real therapeutic effect from the placebo effect in these treatments.

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Materials and Methods

Patients with cervical pain of less than 3 weeks of evolution, and who had not suffered from cervical pain during the previous six months, were eligible for inclusion in the patient population. The period of inclusion to the trial lasted from January 1993 to January 1994. A clinical history file was worked up, a physical examination carried out and X-rays of the cervical spine were taken from front and profile in each patient. The laboratory analyst additionally carried out the following tests: haemography, erythrocyte sedimentation, phosphatase alkaline, uric acid, Rosse Ragan and antinuclear antibody.

Patients with gout, Pager's disease, neoplasia, injection and any collagen diseases were excluded from the trial. We did not include patients who had received prolonged courses of any kind of corticosteroids during the thirty days prior to the trial. All the patients had a wash-out period for analgesic drugs of at least five days. During the period of the study we did not allow the use of any NSAID, corticosteroids or psychiatric drugs and we did not permit any physical therapy sessions. The patients were randomized by a progressive entrance to a protocol and they were divided into two groups, A and B.

Patients who belonged to group A were given laser therapy with a GaAs diode laser, wavelength of 904 nm; pulsed output, pulse frequency 10,000 Hz and pulse width of 200 nsec; peak power of 20 W, 40 mW average power; irradiated area $150 \mu\text{m}^2$ (power density approximately 26 W/cm^2 ; and angle of divergence of 6° . We used the point irradiation technique with a dose

of 4 J/cm^2 per point. We irradiated the painful area using a 2 cm grid system, so points were separated by approximately 2 cm. The frequency of application was five times a week with one session a day from Monday to Friday with a total number of ten sessions. Patients that belonged to group B were treated with sham irradiation with a deactivated laser system. Neither the patients nor the operator knew which group they belonged to. The deactivated laser system did not emit radiation, but the electrical circuit, timer and alarm worked as usual so that to all intents and purposes it was exactly identical to the real system.

In both groups the therapist and the patients were protected with appropriate safety glasses during the session. Pain was evaluated through a linear colour scale at the beginning and at the end of the treatment from which data we evaluated the percentage of relief. The response to the treatment was determined according to the percentage of pain relief graded as follows: 0-30% relief - 'bad'; 31-60% relief - 'fair'; 61-90% relief - 'good'; and 91 - 100% relief - 'excellent'.

The treatment was considered effective when the response was either 'good' or 'excellent', in other words with a pain relief evaluation from 61-100%. The patients in whom results were effective were then followed during six months in order to evaluate the recurrence of their painful condition. They attended our institute at least once a month for their evaluation interview.

Results

During the defined period we incorporated 79 patients into the study group with acute cervical pain that

Table 1: Aetiological diagnosis of cervical pain in both groups.

Group				Others
	Arthrosis	Alteration of the axis	Muscular Contracture	
Group A	20	14	20	—
Group B	17	17	23	1
Total	37	31	43	1

Table 2: Groups A and B compared by age (average yrs old), sex and initial average pain score (scale of 1 to 10).

Group	Age	Sex		Initial pain
		M	F	
Group A	55.81	64.86	53.14	9.35
Group B	51.00	55.88	44.11	9.09

Table 3: Groups A (actual treatment) and B (sham treatment) groups compared by percentage points of pain relief and overall treatment efficacy.

Group	Response				Therapeutic efficacy
	Excellent	Good	Fair	Poor	
Group A	67.57	27.03	5.40	0	94.6*
Group B	17.65	17.65	41.18	23.53	35.3*

*p = < 0.001

Grading: excellent = 91%~100%; good = 61%~90%; fair = 31%~60%;
poor = 0%~30% or exacerbation.

fulfilled the criteria of admission. We randomized 40 patients to group A and 39 patients to group B. In group A, 3 patients were excluded from the treatment. Two gave up, and one used an injectable NSAID, so 37 patients were evaluated in total. In group B, 5 patients were excluded during the study. Two abandoned treatment and three needed to use NSAIDs, thus making 34 the number of patients to evaluate in control group B.

Table 1 gives the aetiological diagnosis of the cervical pain types, comparing both the treatment and the placebo groups. In Table 2 both of the groups are shown compared according to age, sex and initial pain: there was no statistically significant difference. Table 3 shows both groups compared according to pain response (relief percentage) and the overall efficacy of the therapy (percentage of patients who achieved pain relief of greater than 60%) from which it can be seen that the

LLT group responded significantly better than the placebo group. Figure 1 shows the two groups compared graphically graded by the efficacy of the treatment, and Figure 2 shows graphically the overall efficacy in Group A (LLT group) as 94.6% (combining the 'excellent' and 'good' scores (from Figure 1 and Table 3) whereas in Group B it was 35.3%. The difference was statistically significant with $p = < 0.001$.

No patient reported any side effects that could be attributed to the irradiation.

All the patients in both groups with effective treatments (good and excellent responses) were followed during the six months after the treatment. In group A, in 5 of 35 patients (14.28 %) the pain recurred from the fourth month. In group B, 7 of 12 patients (58.33 %) had pain recurrence; in the majority (5 patients) recurrence was seen in the first two months.

Fig 1: Efficacy grading compared for the LLLT treatment and placebo groups.

Fig 2: Total efficacy compared for LLLT treatment and placebo groups.

Discussion

The relief of osteoarticular pain that was achieved with low incident levels of GaAs and other laser irradiation has been reported by many authors for over a decade.⁽⁵⁻⁹⁾ However, serious questions have been presented about the real therapeutic effect that this new modality offers.⁽¹⁰⁻¹²⁾ Many of the reported studies lack scientifically rigid protocols. There were a number of other flaws: the groups treated were heterogeneous, with different pain sites; other therapeutic modalities were applied at the same time as the LLLT; different doses and different exposure times were used to treat the same pathology; and many studies were not randomized or double blinded. Of course, there are notable exceptions to these shortcomings.

In the present study, specific criteria of inclusion and exclusion were defined. We evaluated the pain of a single site; the patients were assigned to the treatment or placebo groups in a totally randomized fashion and laser therapy was indicated with the exclusion of any other type of concomitant treatment. The protocol was developed with a true double blind technique i.e. the real and sham lasers were identical in every respect with the exception of the actual emission of an active laser beam; patients from the total population were randomly assigned to the real or sham treatment groups; neither the patient, the laser therapist nor the pain score interviewer was aware which group the patients belonged to; and the code was not broken until after all evaluations had been made. Finally, the two groups were statistically comparable from the point of patient demographics. The authors were able to complete a meticulous follow up during the six months following the final irradiation session. Based on these points the

authors feel that the obtained results are scientifically valid and are therefore equally valid as a basis for discussion and comment.

In a separate retrospective study reported earlier and applied in 938 patients with osteoarticular pain entities who were irradiated with GaAs LLLT, an overall efficacy rate was reported of 88.20 % for acute pain and 69.27 % for chronic pain.⁽¹³⁾ In that study LLLT gave an efficacy rate of 100% in the relief of acute cervical pain in 75 patients. This fact strongly demanded the authors' attention and that was why they decided to investigate designing and applying a study with a strict double blinding protocol for LLLT in acute cervical pain alone.

The majority of double or single blind studies that have been published have been based on patients with chronic pain and efficacy rates have been reported ranging from 60% to 85% in lumbar pain,⁽¹⁴⁾ knee pain⁽⁶⁾ and postherpetic neuralgias.⁽⁹⁾ As regards acute pain, double blind studies can be identified irradiating patients with epicondylitis with efficacy rates ranging from 65% to 82%.^(15,16) The present study, to the authors' knowledge, is the first report of double blind treatment with laser therapy focusing on acute cervical pain. The high efficacy that we found in the irradiated group, (94.6%) compared with the response of the placebo group (35.30 %), defines an important real therapeutic effect ($p < 0.001$; $RR = 0.08$; 0.02 ; 0.33). However, it is important to point out that in the placebo group, i.e. the group who did not receive real treatment, more than one-third of the patients reported significant pain relief. The authors suggest that this high response is possibly associated with the so-called placebo effect, or possibly with a psychosomatic autolimitation of pain

Fig 3: Overall efficacy of both groups compared with the recurrence rate and recurrence interval. Although there was a comparatively high placebo effect, the recurrence rate was significantly higher and occurred sooner for the placebo group compared with the LLLT group.

and perhaps with a combination of both at the same time.

In the six month post-therapy follow up, significant differences were seen in the latency of effect between the LLLT treated group and the placebo group. There was recurrence of pain in less than one in five (14.28%) in group A but in more than half (58.33%) in group B ($p = < 0.005$) which might suggest that the alleviation of pain in those patients who received the simulated irradiation could possibly be associated more with the placebo effect than with autolimitation of the pain; these data further suggest that the analgesic effect in the patients who received actual GaAs LLLT has a longer period of effectiveness, also known as latency. Figure 3 graphically compares the immediate efficacy of LLLT compared with the follow-up data.

Despite an extensive search of the literature, the authors could not find any reported work that pointed out results associated with other conventional therapies (NSAID, physical therapy and so on) specifically in acute cervical pain, however the authors presume that these therapeutic modalities are not in general superior to LLLT in either their consistence and immediate or latent efficacy. There is however a report on the comparison between LLLT and conventional physical therapy for a series of acute injuries of various aetiologies in the accident and emergency service of a major UK hospital which pointed to an initial improvement with

LLLT which halved the bed rest time requirement compared with conventional physical therapies.⁽¹⁷⁾

It is important to point out the absence of side effects associated with laser therapy. Never-the-less the authors would like to stress the importance of taking reasonable precautions and protecting the patient's eyes to avoid accidental damage, even with LLLT systems and their associated low output powers. As a side note the authors would like to say that they used smaller doses than the ones used and reported previously and also smaller than those doses reported by most of the other authors, but still obtained excellent results: the significance of these data will be discussed in a future paper.

In conclusion we say that irradiation with the GaAs laser, with the doses and techniques that were used in the present study, can be applied as a treatment of choice in patients with acute osteoarticular pain of cervical localization caused by arthrosis, alteration of the vertebral axis and muscular contracture. The authors believe that a real efficacy of this therapy has been demonstrated, despite the emergence of a fairly significant placebo effect. The much stronger latency effect of the LLLT compared with the placebo group bears this statement out. The authors acknowledge the comparatively small patient population, and that studies with much larger patient groups are necessary to confirm these preliminary results.

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