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Diode Laser in Cervical Myofascial Pain: A Double-Blind Study versus Placebo

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Summary: We present a double-blind trial in which a pulsed infrared beam was compared with a placebo in the treatment of myofascial pain in the cervical region. The patients were submitted to 12 sessions on alternate days to a total energy dose of 5 J each. At each session, the four most painful muscular trigger points and five bilateral homometameric acupuncture points were irradiated. Those in the placebo group submitted to the same number of sessions following an identical procedure, the only difference being that the laser apparatus was nonoperational. Pain was monitored using the Italian version of the McGill pain questionnaire and the Scott-Huskisson visual analogue scale. The results show a pain attenuation in the treated group and a statistically significant difference between the two groups of patients, both at the end of therapy and at the 3-month follow-up examination. **Key Words:** Laser—Infrared laser beam—Pain—Chronic pain—Placebo—Double blind study.

The application of light radiation in medicine was a consequence of continuous efforts to find increasingly less invasive therapeutic techniques.

Since the mid-1960s, a number of experimental studies have been performed to ascertain the biological effects of laser light and the mechanisms underlying certain of its therapeutic results. Mester et al., using 15 experimental biological models (1), found that in the 0.5–5 J/cm power range, laser radiation stimulates cellular function of the whole of the tissue irradiated; at higher powers, while not damaging the tissue, it reduces or even stops biological functions. According to Mester et al. (1), the photochemical effect of noncoherent monochromatic light, obtained from a halogen lamp screened with interferential filters, is about 75% that of coherent light of the same wavelength and emission power.

Bolognani et al. (2) used an infrared diode laser (wavelength, 904 nm) on experimental preparations in vitro and in vivo and found an increase in ATP and Na+ and K+-activated ATPase levels after irradiation.

Kudoh et al. (3) observed a charge of Na-K ATPase in the rat saphenous nerve after treatment with a GaAlAS diode laser (830 nm). The authors stressed that this phenomenon may be considered very important for the attenuation of pain.

Stimulation of cellular energy processes hence appears to represent the action fulcrum of the low-power laser in the field of photochemistry; in the treatment of nonmalignant chronic pain, however, this assumption is not sufficient to fully explain the therapeutic effects obtained.

Walker (4) carried out a double-blind study of 36 patients with chronic nonmalignant pain using a He-

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Ne laser at a power of 1 mW and a 4-mm^2 spot. The patients were subdivided into two groups. In the first group, the irradiation was directed at the skin areas over the radial, ulnar, median, and saphenous nerves bilaterally and the painful zones. The second, or placebo, group received the same treatment, the only difference being that the areas of skin irradiated were not innervated by these peripheral nerves. The 24-h urine levels of 5-hydroxyindoleacetic acid (5-HIAA) were also measured before treatment, after five treatments, and after 10 treatments. A significant difference was found in the pain trends of the two groups. In patients with a good result, urine 5-HIAA increased from a baseline range of 2–10 ng/ml to a range of 25–30 ng/ml after 10 sessions; this suggests that laser radiation may have a stimulating effect on the cerebral serotonin metabolism.

Other authors have studied the effect of low laser irradiation in double-blind tests on chronic pain due to rheumatoid arthritis (5), on radicular and pseudoradicular syndromes (6), and on postherpetic neuralgia (7), finding significant differences in comparison with control groups.

These results stimulated us to assess the efficacy of low-power laser irradiation. We chose to adopt an infrared diode laser to treat chronic myofascial pain with a cervical location for several reasons. This painful syndrome is widespread, and patients take an excessive amount of anti-inflammatory analgesic drugs long term for pain relief, exposing them to iatrogenic damages. Second, the infrared radiation penetrates more deeply in tissues to the muscle level, as reported by Scardigno (8). Finally, the diode laser is less expensive and widely available.

MATERIALS AND METHODS

Patients

We treated 27 women suffering from painful myofascial syndromes in the cervical region (the affected muscles were the trapezius, the splenius of the head and neck, the sternocleidomastoid, the scapula levator, and the supraspinatus) as a result of mild cervical arthrosis or poor posture. Radiological examination showed straightening of the column due to loss of normal lordosis and one early stage of discopathy.

We excluded patients with radicular compression pathologic findings, a slipped disk with neurological impairment, or even early signs of a reflex sympathetic dystrophy of the upper limbs such as vasodilation with increasing temperature, hyperidrosis, and edema according to Merskey (9).

The patients, selected by these criteria, were randomly subdivided into two groups. Group A (13 patients, mean age, 43.69 ± 12.75 years and mean duration of pain, 78.84 ± 51.02 months) submitted to a 12-session cycle of laser therapy. Group B (14 patients, mean age, 49.57 ± 9.15 years, mean duration of pain, 69.85 ± 53.23 months) submitted to 12 sessions of placebo laser therapy.

TREATMENT TECHNIQUE

During clinical examination, the muscular tender points in the cervicobrachial region of each patient were found by deep palpation; their location was noted on a graph.

A pneumatic dynamometer was used to measure the number of kilograms of pressure, exerted on a muscular surface area of approximately 3 cm^2, producing pain in the tender areas of all patients. The dynamometer is equipped with a scale of from 1 to 100, each interval corresponding to 100 g. This instrument is a prototype we set up and represents the development of similar spring instruments whose performances are not constant in time. The four most painful tender areas selected in all patients required pressure ranging from 1,200 to 3,800 g. Each of these preselected tender areas were irradiated with 1 J of energy. Five bilateral acupuncture points homometameric to the cervical zone were selected: 4 large intestine (Hegu), 11 large intestine (Quchi), 14 large intestine (Binao), 3 small intestine (Houxi), and 5 triple burner, each irradiated with 0.1 J (10).

The total energy emitted at each session was hence 5 Joules. Each patient was treated with 12 sessions, three sessions a week on alternate days.

CHARACTERISTICS OF THE LASER APPARATUS

We used a Nuova Vitiemme R infrared laser with the following characteristics: laser diode, STC-LE 25; duration of impulse, 200 ns; wavelength, 904 nm; emission frequency, 1,000 Hz; peak radiating power, 25 W; and pilot current, 40 A; number of clips, 3. The laser was equipped with an accessory emission regulator with two positions: A, emission; B, no emission.

PLACEBO TECHNIQUE

The placebo treatment was made possible by this regulator; the conductors of the experiments were

TABLE 1. *Means and SDs of scores on the McGill pain questionnaire in the two groups of patients prior to therapy*

McGill parameters	Group A	Group B	*F* significance
No. of words	12.76 ± 2.35	11.42 ± 3.43	0.251
Total score	29.84 ± 9.58	27.71 ± 11.20	0.61

The univariate *F* test with (1.25) degrees of freedom was used.

TABLE 2. *Means and SDs of scores on the McGill pain questionnaire in the two groups of patients at the end of therapy*

McGill parameters	Group A	Group B	*F* significance
No. of words	6.53 ± 4.05	11.64 ± 3.83	0.002
Total score	13.53 ± 11.43	25.71 ± 10.41	0.008

The univariate *F* test with (1.25) degrees of freedom was used.

not told which position gave emission, and the operational warning light was disconnected to ensure that the "on" position could not be identified.

The procedure was exactly the same in both groups, with the sole exception being that group B patients submitted to 12 sessions with the apparatus off.

PAIN MONITORING

Pain was monitored by means of two different assessment methods: the McGill pain questionnaire calibrated for Italy by Maiani and Sanavio (11), administered before and after the cycle of treatment, and the Scott and Huskisson visual analogue (12), administered before the cycle of treatment, at the beginning of each session, and 3 months after the end of the cycle.

STATISTICAL ANALYSIS

The mean and standard deviation of all the measured parameters were calculated for both groups, and the significance of the differences between the groups was then calculated. To avoid the risk of calculating significance incorrectly, the data of the Scott and Huskisson test have been elaborated on further with a multiple comparison method: the Bonferroni *t*-test with (1.25) degrees of freedom.

The Hotelling *t*-square test with transformation in *F* statistic was performed to make evident whether a statistically significant therapeutic effect was present in each group.

In each group the corresponding values to the measurements effected at the first session (before therapy) were compared with the measurements at the last session (end of therapy) and at the follow-up examination 3 months later.

RESULTS

The results were as follows: the results of the McGill questionnaire given prior to therapy (Table 1) show that pain intensity was substantially similar in the two groups of patients, as there were no differences in *F* significance.

Table 2 shows the McGill values in the two groups after treatment; there is a significant difference between the two groups for the numbers of describers chosen ($p = 0.002$) and the total pain intensity score ($p = 0.008$), which remain substantially unchanged at the end of therapy in placebo

TABLE 3. *Pain trend, measured with the Scott-Huskisson test, in the two groups of patients*

Session	Group A	Group B	Bonferroni *t*-test significance
1	46.69 ± 26.24	29.21 ± 12.61	< 0.05
2	36.38 ± 27.84	34.35 ± 18.54	NS
3	37.92 ± 27.19	32.78 ± 23.70	NS
4	28.84 ± 20.90	35.64 ± 20.95	NS
5	28.69 ± 17.34	36.21 ± 23.29	NS
6	26.46 ± 23.59	36.50 ± 21.12	NS
7	17.23 ± 16.22	33.21 ± 20.82	< 0.05
8	21.15 ± 16.13	36.78 ± 23.93	NS
9	22.84 ± 16.88	34.14 ± 21.18	NS
10	15.00 ± 15.98	37.71 ± 21.86	< 0.01
11	13.69 ± 18.52	37.07 ± 17.83	< 0.01
12	9.46 ± 13.17	37.42 ± 16.58	< 0.001
3 mo later	8.46 ± 10.76	35.57 ± 18.28	<0.001

The significance of the difference between the two groups was calculated with the Bonferroni *t*-test for multiple comparisons with (1.25) degrees of freedom.

TABLE 4. *Hotelling t-square tests with transformation in the F statistic performed in each group of patients*

Group variables analyzed	No. of patients	Degrees of freedom	Hotelling *t*-square	*F* value	p value
A					
Before vs. end of therapy	13	12	26.6160	26.6160	0.0002
Before vs. after 3 mo	13	12	35.2392	35.2392	0.0001
B					
Before vs. end of therapy	14	13	2.2774	2.2774	0.1552
Before vs. after 3 mo	14	13	1.0491	1.0491	0.3244

In the treated group (A), there is a significant difference between the pain levels before therapy and at the end of therapy and 3 months later. In the placebo group (B), there are no significant differences in the pain levels measured at the same time.

patients but dropped to about 45% of the baseline level in treated patients.

Table 3 shows the mean pain intensity values measured with the Scott-Huskisson pain analogue and the significant differences between them for each session and both groups. At the seventh session, a significant difference of $p = 0.036$ was found between the two groups; by the 10th session, this difference had become even more significant, and it remained at the higher level until after the conclusion of the cycle of therapy and the 3-month follow-up examination.

Table 4 shows the mean values of the assessment of the result of the treatment; this parameter also shows a significant difference between the patients who submitted to laser therapy and the placebo patients.

DISCUSSION

Our results confirm that the diode laser is effective in the treatment of cervical myofascial syndrome and that its efficacy is not the result of some incidental or concomitant factor such as the doctor–patient relationship, spontaneous symptomatological remission, or the psychological impact of the use of machine.

In the group of patients who submitted to placebo treatment, there was in fact no appreciable result, the total score for pain dropping by only two points (Tables 1 and 2), i.e., 7.5% of the baseline level. In the treated group, the McGill questionnaire shows that the pain level at the end of therapy had dropped to about 20% of the original level.

These results point out the possibility of achieving a fair healing of the myofascial pain syndrome using "noninvasive" means such as a low-power infrared diode laser, avoiding above all the use of nonsteroid anti-inflammatory analgesic drugs.

There is hence an urgent need for further work to establish the true importance and preferential clinical indication of each parameter of laser stimulation.

Wavelength, emission frequency, energy dosage, and the power of the apparatus must not be left to personal empirical logic but must be subjected to rigorous scientific verification aimed at an optimization of results.

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