GALLIUM ARSENIDE LASER TREATMENT OF CHRONIC LOW BACK PAIN: A PROSPECTIVE, RANDOMIZED AND DOUBLE BLIND STUDY

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Patients of more than 60 years of age and affected by chronic low back pain were randomly assigned to two groups. Group A, consisting of 38 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 cm^2 in area, and an angle of divergence of 6°. The laser was applied in the point technique with a dose of 4 J/cm^2 per point in the area of pain. Group B, consisting of 33 patients, was treated with sham irradiation with a deactivated laser system. Neither the patient nor the operator knew to which group each patient was randomly assigned. The use of analgesic drugs and physical therapy was excluded in both groups. Ten daily consecutive sessions were carried out once per day. Pain was evaluated through an analogue and visual scale at the beginning and at the end of the treatment. Laser treatment was considered effective when pain relief was more than 60%. A follow up was carried out over the following 6 months. The treatment was effective in 71% of patients in group A, and 36.4% of group B ($p < 0.007$). The pain disappeared completely in 44.7% of group A and 15.2% of group B ($p < 0.01$). During the six month follow-up period, in those patients in whom the response to the treatment was effective, the pain recurred in 34.8% of group A and in 70% of group B. No cutaneous, ophthalmologic or systemic side effects were observed. These results suggest that irradiation with GaAs laser at the doses used and techniques applied in this study, relieves chronic low back pain in older patients in a statistically significant percentage of the patients but without causing any adverse side effects.

Key words: Low back pain, gallium arsenide laser, low level laser therapy, osteoarticular pain, chronic pain

Introduction

Approximately 80% of adults at some point of their lives complain about low back pain. Generally, the clinical manifestation is acute and limited, but in 10% of cases the pain becomes chronic and more repetitive.[1-5] Up to 33% of episodes of acute low back pain resolve within a week and during this time the majority of affected persons tend to self-treat with non-steroidal anti-inflammatory drugs (NSAIDs), hot packs and massages. Patients that consult their family doctor frequently received the same therapies with other kinds of physical measures and muscle relaxant drugs being prescribed. In patients whose back pain persists beyond 12 weeks, the prospects of full recovery dwindle rapidly with the passage of time.

Chronic low back pain is seen more frequently in the elderly population and the majority of these patients suffer from arthrosis, osteoporosis and paraspinous muscle contracture.[6] A small percentage of these low back pain entities have their aetiology in pathologies of a greater hierarchy such as multiple myeloma, bone metastasis, Paget's disease, stenosis of the spinal canal due to spondilolysthesis or severely herniated discs.[7]

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In patients over 60 years of age with chronic low back pain, a limited diagnostic evaluation is appropriate. After taking a detailed and accurate medical history and physical examination, simple X-ray of the lumbar spine and standard blood chemistry work-up give adequate information for initial therapy, and only a small numbers of patients need studies of greater complexity such as CT scan or magnetic resonance imaging (MRI).[8-14]

In 85% of cases of chronic low back pain it is not possible to establish clear and irrefutable aetiological diagnoses and the most common form of chronic low back pain is related to degeneration of osseous, articular and ligamental structures of the lumbosacral spine.[14]

Management of chronic low back pain presents a formidable challenge because no single universally accepted therapeutic regimen exists which is capable of giving consistent and repeatable efficacy. A lot of therapies have been proposed for the treatment of low back pain, including: NSAIDs,[15-19] muscle relaxant drugs,[16-18] antidepressant drugs,[17,18,20,21] epidural corticosteroid injections,[17,18,22,23] physiatric measures such as infrared, ultrasound, TENS,[24-17-25-26] massages and chiropractic manipulations,[25-29] immobilisation with different types of corsets[26,30,31] and programs of fitness and physical education.[17,27-29,32,33]

The use of LLLT in the specific relief of osteoarticular pain is growing world-wide with a group of reports suggesting that therapy with the GaAs diode laser in patients with chronic low back pain can relieve the pain in 70 to 90 % of the cases with consistency, although it must be said that the majority of these studies were not done under double blind protocols.[34-37]

The objective of this presentation is to discuss the results of a prospective, randomized and double blind study in patients in their 60's affected by chronic low back pain and irradiated with GaAs laser.

Materials and Methods

Patients of more than 60 years of age and affected by low back pain with a history of more than 3 months were studied. Medical files, physical examination, laboratory analysis and x-ray were performed. We excluded patients with: 1) any suspicion of cancer, osteomyelitis, gout, Paget's disease or collagen disease, 2) symptoms or signs of neurological deficits in the lower limbs, 3) use of long action corticoids taken within the thirty days prior to the start of the study. A wash-out period of 5 days was done for any patients already on NSAIDs.

Patients were randonly assigned to two groups, A and B. Patients belonging to group A were irradiated with a pulsed GaAs diode laser, wavelength 904 nm, pulse frequency 10,000 Hz and pulse width of 200 nsec, peak power of 20 W, average power 40 mW, spot size 150 μm^2 in area and an angle of divergence of 6°. The laser was applied in the point contact irradiation technique with a dose of approximately 4 J/cm^2 per point. We irradiated the painful area using a 2 cm grid system, so points were separated by 2 cm. Patients that belonged to group B were treated with sham irradiation with a deactivated laser system. Neither the patients nor the operator knew to which group they belonged. 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 patient were protected with appropriate safety glasses during the session. The use of analgesic drugs and physical therapy was excluded in both groups.

The therapy regimen consisted of five sessions a week during two consecutive weeks. Pain was evaluated through a visual analogue scale at the beginning and 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: 0-29% relief – poor; 30-59% relief – regular; 60-89% relief – good; and 90-100% relief – excellent. The treatment was considered effective when the response was good or excellent, in others words with a pain relief evaluation from 60-100%. No restriction was placed on the patients' movements, apart from the ban on oral analgesics or NSAIDs. T he patients from both Groups A and B, in whom results were graded as effective, were then followed during a further 6 months in order to evaluate the recurrence of their painful condition. They attend our office at least once a month for their evaluation interview. Patients with regular or bad therapeutic responses in both groups were submitted to CT scan or MRI in order to evaluate the configuration of the spinal canal and to define any bony alterations.

Results

During the defined period we incorporated 85 patients into the study with chronic low back pain that fulfilled the criteria of admission. Forty-three patients were randomly assigned to Group A and 42 patients to Group B. In Group A, 5 patients were excluded from the study, 2 for desertion and 3 who used NSAIDs, so 38 patients were evaluated in total. In Group B 9 patients were excluded during the study. Three abandoned treatment and 6 needed to use NSAIDs, thus making

Table 1: X-ray findings in the treatment (A) and placebo (B) groups.

Radiological findings	Group A	Group B
Osteopoenia	31.58%	30.30%
Osteophytes	63.16 %	66.66%
Narrowing of disc spaces	34.21%	33.33%
Spondylolisthesis Grade I	5.26%	3.03%
Normal	7.60%	8.25%

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

Group	Age	Male	Female	Initial pain
A	63.20	42.11	57.89	7.9
B	64.33	48.49	51.51	8.1

Table 3: Groups A (laser treatment) and B (placebo) compared by percentage of pain relief and therapeutic efficacy.

Group	Pain Score†				Therapeutic efficacy§
	Poor	Average	Good	Excellent	
A	13.15%	15.79%	26.32%	44.74% *	71.06%‡
B	30.30%	33.33%	21.21%	15.16%*	36.37%‡

† 0-29% relief – poor; 30-59% relief – average; 60-89% relief – good; 90-100% relief – excellent
*§ Combination of 'good' and 'excellent' scores. * $p < 0.01$, ‡ $p < 0.007$*

33 the number of patients to evaluate in the control placebo group. Table 1 gives the radiological findings 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 were no statistically significant differences. 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%). Treatment was effective in 71.06% of patients of group A and 36.37% of group B ($p < 0.007$). The pain disappeared completely in 44.74% of group A and 15.16% of group B ($p < 0.01$) (Figure 1). No patient reported any side effects that could be attributed to the irradiation. During the 6 month follow up 34.78% of the patients of group A with effective responses to treatment (i.e. combination of good and excellent responses), relapsed to a greater pain score than after finishing the study. On the other hand, the percentage of relapse in group B was 70% (Figure 1). There were no significant differences in the findings of CT scan and MR imaging done in patients of both groups with regular or bad therapeutic response: one patient of group A demonstrated significant disc herniation and the others patients had arthritic- and osteoporotic-related morphological changes. In patients of group B, MRI showed severe stenosis of the spinal canal in one patient, a significant disc herniation in another and arthrosis and osteoporotic changes in the rest of the patients.

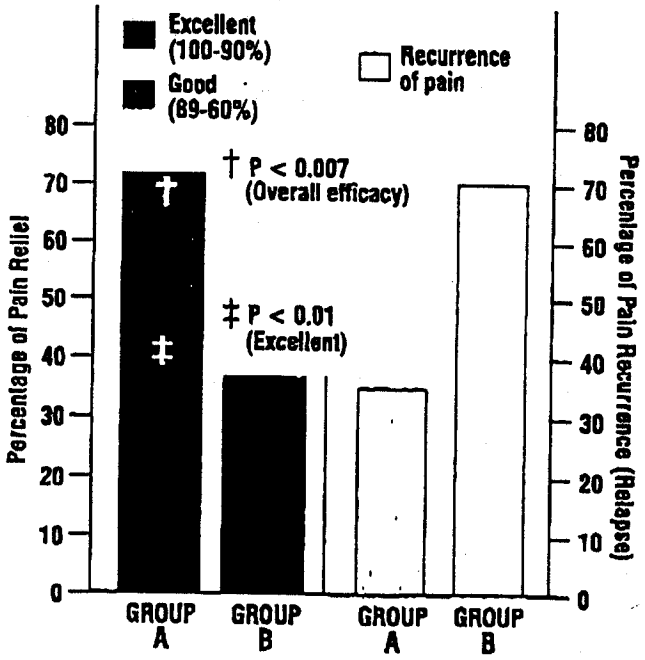

Fig 1: Group A (LLLT) and Group B (Sham) compared from overall efficacy and recurrence rate during the 6 month follow-up. There was a statistically significant difference in both the 'Excellent' pain relief and also the overall efficacy.

Discussion

Since we incorporated LLLT into our therapeutic arsenal in 1989 we have treated up to date more than 4,000 patients with different pathologies, the majority of

them affected by chronic osteoarticular pain. In a retrospective study reported earlier and applied in 938 patients with osteoarticular pain who were irradiated with GaAs laser we found different therapeutic responses according of the site of the pain and time of its evolution.[37] From the data generated by these uncontrolled results we decided to study with strict protocol in a randomized and double blind method groups of patients with osteoarticular pain of the same site and time of evolution with the aim of defining the real therapeutic effect of LLLT in these ailments compared with the so-called placebo effect, supposedly extremely strong with 'laser'.

We previously reported the results of a controlled LLLT study in patients affected by acute cervical pain and demonstrated a significant effect in the group of irradiated patients.[38] The present report is the second double blind study in patients with osteoarticular pain concluded by our group. We chose for this study patients older than 60 years old affected by chronic low back pain because of the frequency in which this problem is encountered and because elderly people are more vulnerable to the potential adverse side effects of NSAIDs which are often taken in a habitual and repetitive way by patients with low back pain. For this reason, the possibility that LLLT is capable of relieving pain in a high percentage of patients, without adverse side effects, was to us very attractive. However the analysis of our results shows that only 44.74% of patients achieved complete relief, a percentage that does not significantly outnumber what can be achieved with patients taking NSAIDs on a regular basis. However, if we add the patients who achieved more than 60% of relief from their back pain after 10 sessions of LLLT, we note that more than 70% of affected patients benefit from LLLT. If we also take into account, during the follow up period of six months without any therapy of any kind, the low percentage of LLLT patients in whom pain returned to a level higher than that after treatment (36.4% in Group A compared with 70% in the placebo Group B) and we failed to demonstrate any adverse effects of laser irradiation, we can confidently suggest that we are looking at a therapeutic alternative that deserves consideration. Furthermore, laser irradiation is totally noninvasive, easy to apply, well-tolerated by elderly patients, is not ionizing and the doses are not cumulative. Because of these benefits we can give more therapy sessions without the possibility of genetic or any other kind of damage. A review of the literature shows only one report that specifically demonstrated histological alterations in chicken embryos irradiated with HeNe laser,[39] but the experimental conditions (direct irradiation to the embryo with very high doses) are impossible to reproduced in the clinical practice. On the other hand, studies have been produced which show no damage following very high clinical doses of GaAlAs laser *in vivo*.[40,41]

As in our previous reports,[37,38] we failed to demonstrated any adverse side effects related to GaAs LLLT.

In the present study the two groups were statistically comparable and 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 with a protocol which was developed with a true double blind technique. We also completed a meticulous follow up during the six months following the final irradiation session.

Based on these points we believe that the results we obtained are scientifically valid and demonstrate a real therapeutic effect of GaAs laser irradiation on geriatric patients affected by chronic nonspecific low back pain compared with a similar population under placebo treatment with a statistically significant difference (71.06% versus 36.37% respectively; $p < 0.007$). Studies with a greater number of patients are of course necessary to confirm these results with greater statistical meaning to enhance the scientific significance as compared with the very clear clinical significance, but the authors feel that the data from the present somewhat limited study certainly warrant further investigation.

Conclusion

These results suggest that GaAs LLLT in the doses and techniques described above relieves chronic low back pain in a statistically significantly percentage of older patients without causing side effects. LLLT must therefore be considered specially in the elderly population when risk from, intolerance and contraindications to the use of NSAIDs are present..

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