

Clinical case series: the effect of MLS[®] treatment on 30 patients with lumbosacral sciatic pain.

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ABSTRACT

Lumbosacral sciatic pain is a condition associated to spine degeneration which is affecting people daily life and activities. In fact, often pain is not only affecting the lumbar zone, but it is also irradiating down to the lower limb and can influence movement flexibility and general physical function.

Conservative treatment involves the use of anti-inflammatory drugs and different physical therapy approaches. Nevertheless, most severe cases need to be treated with surgical intervention.

This case collection reports on the use of MLS[®] therapy in 30 cases of lumbosacral sciatic pain, where the goal was not only the management of the pain, but also the improvement in physical function with the aim of reaching a better quality of life for the treated patient.

All the patients were treated with 12 sessions of MLS[®] therapy.

Patients improved not only in terms of pain management, but also in function and therefore in every day activity comfort, i.e. better sleep and better walk ability. In terms of pain, before the treatment start, average VAS was 8, while at the end of the treatment cycle, average VAS was 1. The treatment was effective in keeping pain controlled between consecutive sessions.

In conclusion, MLS[®] therapy resulted a useful

approach for the treatment of lumbosacral sciatic pain.

INTRODUCTION

Lumbosacral sciatic pain is one of the most common pathologies, affecting 8 people out of 10 in industrialized countries, causing not only patient discomfort but also economic loss due to work absence. This type of pain affects the lower back, irradiating in the lumbar and sacral portion, and sometimes reaching the gluteus and the lower limbs. It is common to have acute episodes of lumbosacral sciatic pain which can evolve, if not treated correctly acting on the causes of the pain, in a chronic condition. Spinal pain in the elderly is also a widespread and serious issue, as it affects general wellbeing and independence of this part of the population [1]. Additionally, considering population aging and the request for a longer active life, lumbosacral sciatic pain is a more and more significant health issue.

Kuslich et al [2] identified intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root as tissues capable of transmitting pain in the low back. The most common cause for this type of pain is the compression of nerve roots due to degenerated discs or herniated discs, spondylolisthesis or spinal stenosis in the lumbar area. Due to the anatomic conformation of the sciatic nerve, the pain associated to the

compression irradiated to the gluteus muscle and down to the lower limb. In some cases, piriformis syndrome can also provoke sciatic pain, due to the compression of the nerve by the inflamed muscle. Piriformis syndrome is a relatively rare condition resulting in severe unilateral isolated buttock pain shooting in nature, non-discogenic in origin. Most of the times, the symptoms are monolateral, at the site of the affected root, and only some few patients report bilater sciatic pain.

Lumbosacral sciatic pain in most of the cases can be classified as neuropathic pain, namely a pain caused by a lesion or disease of the somatosensory system with high clinical incidence [3], whose pathophysiological mechanisms are not yet fully understood [4]. In many cases, beside pain, other symptoms associated to lumbosacral radiculopathy can include numbness, weakness, and loss of reflexes. About one-fifth of patients who report chronic pain have predominantly neuropathic pain [5,6].

Risk factors such as age, smoking, body weight, height, occupational load and mental stress contribute to lumbar radicular pain [7,8]. Current treatments involve the use of anti-inflammatory compounds either as traditional drugs i.e. NSAIDs and steroids in most severe cases. For example, epidural injection of corticosteroids is a commonly used intervention in managing chronic spinal pain [9]. Additionally, natural products, such as botanic extracts, appear to be promising sources of new drugs [10]. Other treatments used for sciatic pain relieve include chiropractic manipulation, acupuncture, therapeutic exercise and physical therapies. In the most severe cases, surgical intervention is required to solve or alleviate the pain acting on the pain cause.

MLS[®] Laser is a therapeutic device based on knowledge derived from experimental and clinical research which demonstrated the efficacy of the therapy in the treatment of many musculoskeletal diseases [11-14] and allowed to develop advanced treatment protocols. Previously, Viliani [15] used MLS[®] laserpuncture in the treatment of spinal pain,

based on the fact that, from the clinical point of view the laserpuncture seems equivalent to the classical acupuncture approach [16] and reported positive results in terms of safety and quality of life.

We also reported a case report, collected in our center [17], related to a patient presenting the regression of cervical radiculopathy after laser therapy treatment with MLS®. In this new paper, we have specifically reported our experience in the treatment of lumbosacral sciatic pain, which is a very common condition among our patients. In details, this paper reports on the use and results of MLS® laser treatment in 30 patients presenting lumbosacral sciatic pain, looking at aspects such as pain control and functional recovery related to everyday activities i.e. flexibility, sleep comfort, ect.

MATERIALS AND METHODS

Thirty patients presenting lumbosacral sciatic pain have been enrolled in the Centro Medico Adaptogeno, Bayamón, Stati Uniti. Demographic details (i.e. sex, size, age) were collected. Diagnosis was indicated for all the patients, specifying the status of the condition, i.e. acute, chronic or acute exacerbation of chronic pain. Imaging evaluations, such as CT scan, X-ray or MRI, were recorded whenever available. Additionally, patients were evaluated by the specialist performing the treatment before therapy start.

The treatment consisted in 12 MLS® Laser therapy sessions, performed thrice a week with M6 device (ASA Srl, Arcugnano (VI), Italy). MLS® Laser therapy is cleared by FDA and widely used in clinics. M6 laser is a class IV NIR laser with two synchronised sources, one is a pulsed 905nm laser diode (peak power 25W, duty cycle of 50 %), the second is a continuous 808 nm laser diode (peak radiant power 1.1 W). The two laser beams work simultaneously and synchronously with coincident propagation axes. During the treatment, patients and therapists wore safety glasses to prevent eye damage.

The protocol used for MLS® Laser therapy sessions interested the entire area from L2

to S2, covering from 155 cm² to 300 cm², according to the specific area to be treated. The MLS® Laser therapy sessions were either dedicated to lumbosacral arthritis or lumbar/sciatic pain specific treatment with the following parameters:

- Lumbar pain: 1 patient treated. Frequency: 700Hz, exposure time: 10 minutes, Intensity 100%. Robotised head was used to apply a total of 1035 J, with a dose 3.5 J/cm² in scanning mode. Additionally, the handpiece was used to treat 6 points, for 1'40" each, to apply a total of 315J with a dose 16J/cm². The anatomical points for the treatment were identified as follows: the spinal apophysis space from L2 to S2 was divide into three equal parts – top, medial, bottom – and the handpiece treatment was carried out on:
 - 2 points bilaterally above L4
 - 2 points bilaterally above the selected area
 - 2 points bilaterally below the selected area, on gluteus
- Lumbosacral arthritis treatment: 16 patients treated. Frequency: 1500Hz, time: 10 minutes, Intensity 100%. Robotised head was used to apply a total of 1090 J, with a dose 3.5J/cm². Additionally, the handpiece was used to treat 6 points repeated two times, for 43" each, to apply a with a dose 8J/cm² each, delivering a total of 285J. The anatomical points for the treatment were the same described above for lumbar pain.
- Sciatic pain treatment: 12 patients treated. Frequency: 900Hz, exposure time: 10 minutes, Intensity 100%. Robotised head was used to apply a total of 1050 J, with a dose 3.5J/cm². Additionally, the handpiece was used to treat 7 points, repeated two times, for 43" each, to apply a with a dose 7J/cm² each, delivering a total of 320J. The anatomical points for the treatment were the same described above for

lumbar pain, with the addition of a point, homolateral to the pain, along the sciatic nerve, on the posterior face of the inferior limb painful point.

Moreover, one patient received 4 treatments using the lumbosacral pain parameters and 8 sessions with sciatic pain parameters.

Trigger points were treated in all patients with the following parameters: Frequency: 10 Hz, time: 23 s, Intensity: 25%. In the trigger point phase, the hand piece was perpendicular to the treated points.

Most of the involved patients were old and affected by multiple systemic pathologies, such as diabetes, therefore they have not discontinued their routine therapeutic regimen during MLS® treatment.

Pain evaluation was performed before and after each laser session using a Visual Analogue Scale (VAS) scale. It is a scale comprising 10 grades, with 10 representing 'unbearable pain' and 0 representing 'no pain'. It is a pain scale commonly used in the medical field, and it was shown to be a reliable and valid measure of pain [18]. Functional evaluation and global assessment were reported by the specialist as final comment to the treatment cycle.

RESULTS

The demographic characteristics of the 30 patients involved are summarized in Table 1, showing a good balance between males and females and confirming that most of the cases were related to people with 65 years or more. The diagnosis was associated to an acute stage in 26 cases, to a chronic stage in 3 cases, while condition stage was not specifically indicated in 1 case. Pain was present bilaterally in 2 patients.

Specific conditions that were reported in the study population were: radiculopathy, which was observed in 3 cases; diabetic neuropathy, present in 2 patients; degenerative disc disease/discogenic pain, that affected 6 patients.

When imaging results were available, they supported the lumbar vertebrae degeneration (i.e. lumbar spondylosis, vertebral space narrowing) status, presence of spondylolisthesis

Table I - Demographic characterization of patient population

Sex	17 Female 13 Males
Size	7 Small 23 Medium
Available evaluation	3 CT 1 X-Ray 6 MRI
Age	≥65 yrs – 20 patients Older than 40 and younger 65 years – 9 patients <40 years – 1 patient

Table II - Results according to the specific treatment

Treatment	Number of patients treated*	Average VAS before first treatment	Average VAS after last treatment
Lumbar pain	1	10	0
Lumbosacral arthritis	16	9.4	1.5
Sciatic pain	12	7.3	0.3

*1 patients received mixed treatment and has been excluded by this table

and canal stenosis and disc degeneration involvement, such as degeneration and protrusion. Lumbar lordosis was also evidenced, which is recognised to be one of the potential causes of sciatic pain. Some patients had also problems related to the cervical spine area, where osteopenia signs suggested a general degeneration of spine health.

Cauda equina inflammation was also observed in one chronic patient, as this was not an anatomical conflict but rather a tissue condition, beside application of laser therapy, the patient was also referred to a neurologist. After the treatment, the patient reported to be improved and the cauda equina inflammation was reduced.

No adverse effects have been observed during the treatment sessions.

Patients presented to the first treatment session with high level of pain. In fact, before the first treatment session, 29/30 patients reported

pain scores >5 and average VAS was 8.

After the last treatment session, 28/30 patients reported pain scores < 3 and average VAS was 1.

The results corresponding to the specific type of treatment that was performed (i.e. lumbar pain, lumbosacral arthritis and sciatic pain) are reported in Table 2.

All patients reported immediately an improvement in VAS score after the first treatment. In general, after the treatment sessions it was possible to see a general improvement in VAS respect to the value before the laser treatment. Specifically, improvement was mostly evident comparing the pain before and after each session, reaching a control of pain in between treatment sessions.

A general improvement in flexibility of the treated area and in related anatomical sites (i.e. knee) was highlighted at the end of the treatment sessions by specialists and patients.

Some patients reported additional specific effects due to pain relief, such as better sleep, less muscle spasms and improvement in walking and in an overall increase in physical activity.

DISCUSSION

This case series reports the clinical outcome obtained by the application of MLS® laser therapy on 30 patients presenting lumbosacral and sciatic pain, a very common type of pain that patients complaint and for which they seek medical advice. The results further confirm the safety of MLS® laser therapy in the treatment of patients affected by lumbar and sciatic pain, even concerning complex patients presenting multiple pathologies and degenerative conditions, with no adverse effect that have been reported. Also, a patient with cauda equina inflammation, a severe condition that if left untreated can even degenerate into permanent paraplegia, reported a beneficial effect from MLS® treatment and the inflammation itself improved at the end of the laser therapy cycle.

Regarding pain management, our results indicate that laser therapy with MLS® has been beneficial for these difficult patients, providing immediate relief after the various treatments and maintaining stable pain level in between treatments, with a positive overall effect on quality of life. This is a remarkable result, considering that most of the patients in this collection were affected by degenerative conditions, which naturally evolve in progressive chronicity, and taking into account the age of the affected people which, as it could be expected, are mostly old people over 65 years of age. According to the results obtained by most of our patients including the ones affected by neuropathic conditions, such as diabetic neuropathy, systemic tissue pathology is likely to influence the clinical results and, in those cases, the treatment to control the chronic pathology (i.e. stabilization and containment of blood parameters) is an essential component of the therapeutic plan to obtain good results in terms of pain management too.

Beside pain evaluation, flexibility improvement was a key observation, which facilitated patient independence in routine activity. It is important to note that this flexibility improvement was underlined by the therapist even in patients reporting intermittent VAS improvement, suggesting the presence of an objective improvement, independent from patient's own evaluation. These patients' characteristics also played a role in the durability of the results obtained by the laser therapy, in light of the fact that the condition is degenerative, the mitigation of pain in the time between the consecutive treatment sessions is a very positive result. The most severe cases were anyway suggested to attend some additional treatment sessions in order to further improve and maintain the beneficial effects of MLS® therapy.

In a previous case report [17] treated in our center, we already reported the remarkable result obtained in a cervical radiculopathy patient, in relation to both pain and spinal cord narrowing and with this report on lumbosacral sciatic patients we further confirm the value of MLS® therapy in the treatment of back problems. Despite the mechanism of action of the laser in these pathologies had not been fully elucidated, it is suggested that the anti-inflammatory properties which are typical of MLS® therapy can play a key role in the alleviation of lumbar and sciatica pain. Recently, a publication by Kobiela Ketz et al [19] suggested that the reduction of hypersensitivity mediated by laser treatment in a model of neuropathic pain induced by spinal nerve injury could be exerted by modulating the activation of cells, such as macrophages and microglia components. Additionally, the well-known analgesic effect [20] plays an immediate role in relieving pain providing the patient with a positive feedback straight from the first treatment sessions, allowing patients to immediately gain confidence and improve everyday conditions.

CONCLUSION

The results obtained in our clinical practice and reported in this case series show that MLS®

Laser therapy is a useful approach for the treatment of lumbosacral sciatic pain and it is able to promote flexibility. In a useful approach for the treatment of lumbosacral sciatic pain and it is able to promote flexibility. In

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