Rehabilitation with “Software Controlled Short Tension Impulses Therapy” (So.Co.Short) for Lumbar and Cervical Chronic Radiculopathy

Raoul Saggini1,*, Simona Maria Carmignanò2, Marco Supplizi3, Emilio Ancona2, Lucia Cosenza2 and Rosa Grazia Bellomo4

1Physical and Rehabilitation Medicine, Department of Medical Oral and Biotechnological Sciences, Director of the School of Specialty in Physical and Rehabilitation Medicine, “Gabriele d’Annunzio” University, Chieti-Pescara (Italy), National Coordinator of Schools of Specialty in Physical and Rehabilitation Medicine, Italy
2School of Specialty in Physical and Rehabilitation Medicine, “Gabriele d’Annunzio” University of Chieti-Pescara, Italy
3Physiotherapist, Lecturer, Faculty of Physiotherapy “G.d’Annunzio” University-Chieti, Italy
4Physical and Rehabilitation Medicine, Department of Medical Oral and Biotechnological Sciences, “Gabriele d’Annunzio” University, Chieti-Pescara, Italy

*Corresponding author: Raoul Saggini, Gabriele d’Annunzio University, V.le Abruzzo 322, 66100 Chieti, Italy, Tel: +39 0871 3553005-3553007; Fax: +39 335 8339950; E-mail: raoul.saggini@unich.it

Received date: August 07, 2017; Accepted date: August 28, 2017; Published date: August 31, 2017

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Abstract

Background: Recent studies have highlighted a new use of electrical stimulation called electroceutical therapy that uses electrical stimulation similar to frequency modulated electromagnetic neural stimulation (FREMS) that influence and modify the functions of the body. A pilot study was designed aimed to evaluate the efficacy of “Software Controlled Short Tension Impulses Therapy” (So.Co.Short) in subjects with lumbar and cervical radiculopathy in chronic phase treated with two different protocol one daily or and the other every other day. Furthermore, the second endpoint is monitor analgesic intake for 2 month after the end of protocol.

Materials and Methods: 60 patients with chronic cervical radiculopathy were included, aged between 31 and 80 years and 70 subjects with chronic lumbar radiculopathy aged between 28 and 80 years. Patients underwent a session, using a newly-developed biomedical device that allows the application of software-controlled electric impulses of variable tension, frequency and duration “Software Controlled Short Tension Impulses Therapy”- (So.co.Short) for 10 sessions with two modalities of application: daily or every other day. At the beginning (T0) and the end (T1) of the treatment all patients performed Visual Analogic Scale (VAS), Neck Disability Index (NDI) or Oswestry Disability Index (ODI). A drug diary was kept by each subject to monitor analgesic intake at T0 (before 2 weeks at beginning of study) and 1 month after the end of protocols.

Results: Results confirm effectiveness for pain relief and reduction of analgesic intake.

Conclusion: In conclusion, the findings of this study confirm that So.Co.Short is safe and leads to pain relief and improvement of healing in lumbar and cervical chronic radiculopathy. Probably the best application is on every other days, because stimulating the production of growth factors and triggering the relief of pain, must leave enough time for the molecules produced to act on the inflammatory process.

Keywords: Chronic radiculopathy; Pain relief; Electroceutical medicine; Rehabilitation; Low back pain; Neck pain

Introduction

Peripheral radiculopathy is pathology with a multiple and complex etiology and it represents the major cause of neuropathic pain. Patients with neuropathic pain usually are more heavily burdened than patients with nociceptive pain and they suffer more often from insomnia, anxiety, and depression [1,2].

Lumbar radiculopathy can involve both the back and the legs. In addition, both neuropathic and nociceptive pain pathways contribute to lower back and associated leg pain. Generally, the leg pain component is due to neuropathic pain, and the back pain component is due to nociceptive mechanisms [3]. Cervical radiculopathy is defined as a syndrome of pain and/or sensorimotor deficits due to compression of a cervical nerve root. The compression can occur as a result of disc hernia, lumbar spondylolisthesis, instability, trauma, or rarely, tumors. Patient presentations can range from complaints of pain, numbness, and/or tingling in the upper extremity to electrical type pains or even weakness [4,5]. Both cervical that lumbar radiculopathy can be a debilitating disease that can cause patients significant impairment. The damage can be significant both economically, from lost work and wages, and psychologically, from prolonged pain and impaired social functioning. The goal for treatment should be the rapid diagnosis and treatment of this condition in order to facilitate the return of the patient to their normal state of health.

Several studies and systematic reviews show that the management of radicular pain is still controversial [6-8]. Other studies examined the efficacy of Transcutaneous Electrical Nerve Stimulator (TENS) in musculoskeletal disorders and neuropathic pain have been published so TENS has been increased popularity used as a treatment of acute and chronic pain [9-11].

Afterwards, clinical trials showed that frequency modulated electromagnetic neural stimulation (FREMS), as a non-
pharmacological treatment, is a safe and effective therapy for pain in peripheral radiculopathy, leading to the amelioration of symptoms and improvement of peripheral nerve function Bosi et al. [12]. Recent studies have highlighted a new use of electrical stimulation called “electroceutical therapy” that uses electrical stimulation to influence and modify the functions of the body that allow the treatment of various pathologies Through autogenously production of neurotransmitters [13].

Other studies have shown that the factors involved in regenerative processes of peripheral nervous tissue can be stimulated by controlled voltage pulse generator therapy as activation of cell membrane channels, synchronization of vasomotor responses increase of peripheral blood flow and endothelial growth factors [14].

Based on these considerations, a pilot study was designed aimed to evaluate the efficacy of “Software Controlled Short Tension Impulses Therapy” (So.Co.Short) in subjects with lumbar and cervical radiculopathy in chronic phase treated with two different protocol one daily or and the other every other day. Furthermore, the second endpoint is monitor analgesic intake for 1 month after the end of protocol.

Materials and Methods

This pilot study carried out at Universitary Center of Physical and Rehabilitative Medicine of "G.d‘Annunzio" Universitary in accordance with the Helsinki Declaration of 1964. All participants were informed about the study methods and issued their written consent before making the therapeutic protocol.

Inclusion criteria

18 years of age, with chronic lumbar and cervical radiculopathy, pain for more than one month, pain level of at least 3 on Visual Analogic Scale (VAS scale), and written informed consent.

For cervical radiculopathy, we include patients with a neurologic condition characterized by dysfunction of a cervical spinal nerve, the roots of the nerve, or both. It usually presents with pain in the neck and one arm, with a combination of sensory loss, loss of motor function, or reflex changes in the affected nerve-root distribution [15].

For lumbar radiculopathy a condition of the peripheral nervous system that causes the appearance of intense pain at the lumbo-sacral area of the back, which radiates along one of the lower limbs and reaching the foot with motor and sensory deficits [16,17].

Pain level was of at least 3 on Visual Analogic Scale (VAS scale) for both pathological conditions.

Exclusion criteria for treatment were:

- Pregnancy;
- Pacemaker;
- Lack of self-sufficiency in ADL and IADL;
- Severe deterioration of the cognitive state (Mini-Mental State Examination ≥ 24);
- Neurodegenerative diseases, cancer, cardiopulmonary, and renal failure.
- Concomitant inflammatory diseases, administration of non-steroidal anti-inflammatory drugs (NSAID) in the 2 weeks preceding the study;
- Indication for surgical treatment.

Patients` recruitment and sample collection

60 patients with chronic cervical radiculopathy were included, aged between 31 and 80 years (mean age: 53 years, 11 M, 19 F) and 70 subjects with chronic lumbar radiculopathy aged between 28 and 80 years (average age: 57 years old, 15 M, 24 F) (Figure 1).

In the 60 patients with cervical radiculopathy, at magnetic resonance imaging (MRI) was demonstrated the presence of 10 herniated discs, 19 multiple slipped disc, 31 localized protrusions.

In the 70 subjects with lumbar radiculopathy, the MRI revealed the presence of 12 herniated discs, 21 multiple protrusions, 37 localized protrusions.

The patients underwent a session, using a newly-developed biomedical device that allows the application of software-controlled electric impulses of variable tension, frequency and duration – “Software Controlled Short Tension Impulses Therapy”- (So.co.Short) for 10 sessions.

It is a technology consisting of biocompatible electrical signals generated by computerized neuro-stimulators and applied through trans-cutaneous electrodes (Figure 2).

The So.co.Short is software controlled voltage pulse generator with two independent channels, which varies the "pulse patterns", according to the pathology being treated and patient response.

The technical characteristics of the device are: a frequency ranging from 1Hz a 500Hz, amplitude of 0V a 200V regulated by patient depending on the specific perception of the pulse; and a rise time lower than 25 ns. The impulses were managed by specific software, which varied the pulse patterns according to the patient response.
Furthermore, So.Co.Short system differs from other device because it allows positioning the electrodes throughout the peripheral area, following the dermatomeric distribution (Figure 3).

Each session lasted 27 minutes in the cervical radiculopathy group and 31 minutes in the lumbar radiculopathy group.

Clinical assessment
At the beginning (T0) and the end (T1) of the treatment all patients performed:
- Evaluation of balance and gait by administration of Visual Analogic Scale (VAS);
- Assessment of pain and patient-rated disability with Neck Disability Index (NDI) for cervical radiculopathy group. The NDI can be scored as a raw score [18] or doubled and expressed as a percent [19].

Each section is scored on a 0 to 5 rating scale, in which zero means 'No pain' and 5 means 'Worst imaginable pain'. All the points can be summed to a total score. The test can interpreted as a raw score, with a maximum score of 50, or as a percentage.

- Assessment of pain and patient-rated disability with Oswestry Disability Index (ODI) for lumbar radiculopathy group. It is a self-administered questionnaire divided into ten sections designed to assess limitations of various activities of daily living. Each section is scored on a 0-5 scale, 5 representing the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage. Thus, for every question not answered, the denominator is reduced by 5. If a patient marks more than one statement in a question, the highest scoring statement is recorded as a true indication of disability. The questionnaire takes 3.5-5 min to complete and approximately 1 min to score [20].

A drug diary was kept by each subject to monitor analgesic intake at T0 and at T1 1 month after the end of protocols. A specially devised drug diary was used to measure analgesic intake.

Statistical analysis
Statistical analysis was performed by Fischer’s PLSD test. The minimum level of statistical significance was P<0.05. The software used for the analysis was GraphPad Prism (version 5) software (Abacus Concepts GraphPad Software, San Diego, CA).

Results
In the present study, 130 patients with chronic radiculopathy (aged 28 to 80 years) were evaluated and treated. All completed the prescribed therapeutic protocol and performed the second evaluation at the end of the treatment cycle. In all subjects treated, a statistically significant reduction (p<0.05) of the level of pain measured with VAS scale was obtained after each treatment session (expressed in the first two graphs as average trend) (Figure 4).

In the cervical radiculopathy group, 30 patients underwent therapy on alternate days and 30 patients underwent daily treatment. In the lumbar radiculopathy group, 35 patients underwent therapy on alternate days, 35 patients underwent day-to-day treatment.
treated daily ODI score decreased by 46% (severe disability) at T0 to 6% at T1 (minimal disability) \( p=0.037 \) (\( p<0.05 \)). in Figure 7.

The score obtained in the questionnaire Neck Disability Index (NDI) in the cervical radiculopathy group who performed therapy on every other days decreased on average from 54% (severe disability) at T0 to 12% (mild disability) \( p=0.045 \) (\( p<0.05 \)); in the group treated daily NDI score decreased by 52% (severe disability) at T0 to 12% at T1(mild disability) \( p=0.047 \) (\( p<0.05 \).) in Figure 8.

Medicines that were taken by the patient or prescribed by the general physician for pain control comprise mainly non-steroidal anti-inflammatory drugs (e.g. aspirin, ibuprofen) and compound analgesic preparations (e.g. co-dydramol, co-proxamol). All other drugs were excluded.

To calculate drug intake, a percentage formula was used:

\[
\text{Drug intake} \% = \frac{\text{Number of days with drugs}}{\text{Total number of days}} \times 100.
\]

All patients reduced after 2 month the intake of the analgesic by 60%.

Discussion

The evolving development of medical and surgical therapies has significantly improved the physician's ability to manage patients with cervical and lumbar radiculopathy, yet many continue to suffer debilitating symptoms from their disease and chronic pain [21].

Transcutaneous electrical nerve stimulation (TENS) is the application of electrical stimulation of varying frequency, intensity and pulse duration to the skin for pain relief and it is one of the most used approaches in rehabilitation medicine for radiculopathies [22].

Different TENS modalities use varying combinations of frequency and intensity settings on the device to elicit pain relief. TENS is generally believed to be a safe non-invasive intervention which may produce significant analgesia in many patients with moderate predictable pain associated with a range of conditions [23,24].

Tens acts according to this Gate-Control Theory of Pain, activity in large diameter low threshold mechanoreceptive (touch-related) nerve fibers could inhibit the transmission of action potentials from small diameter higher threshold nociceptive (pain-related) fibers through pre and post synaptic inhibition in the dorsal horn of spinal cord. Humans utilize this mechanism whenever they rub their skin to relieve pain. Because nociceptive fibers (A-delta and C-fibers) have a higher threshold of activation than mechanoreceptive fibers (A-beta fibers) Melzack and Wall proposed that it would be possible to selectively...
stimulate mechanoreceptive fibers by titrating the amplitude of electrical currents delivered across the surface of the skin (as TENS). This would prevent signals from nociceptive fibers from reaching higher centre of the brain, thus reducing pain [25].

The device used in this study is similar to Frequency-modulated electromagnetic neural stimulation FREMS and it is based on the new concept of “Electroceutical medicine” involves the use of electrical modalities as a modulator of biological processes. Cell membrane responsiveness to an electrical stimulus is determined by the characteristics of its strength duration curve and electrical characteristics. FREMS, being based on TENS methodology, falls within the generic definition of TENS; nevertheless, the electrical stimulus in FREMS significantly differs from those commonly used in other known electrotherapies, mainly TENS apparatuses. FREMS sends pulses with waveforms which recall the cellular action potential associated with packets of complex stimuli that adapt to the biological characteristics of the patient. Electrical stimulation to influence and modify the functions of the cells by supplying electrical impulses directed to specific nerve fibers. FREMS provides sequences of biphasic electrical stimuli that vary simultaneously and automatically in frequency, pulse duration and amplitude, reaching relatively high intensity (300 V) in association with a very short duration (10-100 µs), maintaining electrical balance in the tissues [26].

This feature is novel with respect to existing electrotherapies, which are normally based on ‘geometrical’ waveforms characterized by lower peak intensity and higher pulse duration. Regarding FREMS, it should be emphasized that specific new mechanisms of action have been described, such as enhancement of micro vascular blood flow measured by laser doppler flowmetry [27].

Bevilacqua et al. demonstrated that VEGF release during FREMS may help explain the positive effects on nerve conduction [28].

Furthermore, the biochemical mechanisms underlying nerve root damage remain, unknown, but some studies demonstrated that TGF-β1, IGF-1, IL-6 and IL-6R are located in the protruded disc tissue and they are related to inflammatory process in response to tissue damage.

Cohen et al. [29] demonstrated, using northern analysis that treatment of various cell lines with IL-6 for 6-48 h resulted in a significant induction of vascular endothelial growth factor (VEGF) mRNA. It has been reported that IL-6 also interferes with pain sensation in rats; for instance, intra-cerebral-ventricular injection of IL-6 induces thermal hyperalgesia. In line with this finding is the results can confirm that So.co.Short can modulate pain and the nerve regenerative processes through the possible release of growth factors (especially endothelial) that modulate blood supply and reduce the inflammatory process by promoting healing.

Conclusion

This study investigated the safety and efficacy of So.co Short and results seem to confirm its effectiveness, probably the best application is on every other day, because stimulating the production of growth factors and triggering the relief of pain, must leave enough time for the molecules produced to act on the inflammatory process. A relevant aspect to take into account when considering any new treatment is cost and side effects: the reduction in the use of pain medication results in a reduction in health costs and the risks associated with drug abuse.

A limitation of our study is that the criteria for inclusion did select patients with painful radiculopathy with different etiology and, assessment was done only with subjective scales, No control group or placebo group is included. Therefore, greater research will be needed in the future.

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J Nov Physiother, an open access journal
ISSN:2165-7025
Volume 7 • Issue 5 • 1000363


