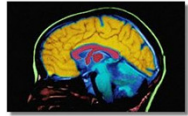


Scrambler Therapy: An Innovative Neuromodulation Approach to Complex Regional Pain Syndrome:



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Abstract

The Institute of Medicine (2011) has estimated that there are 116 million adults in the US with chronic pain at a cost of \$560-635 billion in direct costs and lost productivity. Among those people experiencing chronic pain are those diagnosed with Complex Regional Pain Syndrome (CRPS). This study focused on the application of an innovative neuromodulation technique to reduce pain in people with CRPS. Gate-Control Theory of pain is not adequate to fully understand this chronic pain group. A technique that utilizes an electromodulation approach based upon information and cybernetic theory was developed in Rome, Italy and has been demonstrated to have a higher level of efficacy in reducing the chronic pain syndrome than standard medical approaches in patients with chronic back pain, neuralgia and chemotherapy induced peripheral neuropathy. This technique is called Scrambler Therapy (ST). The ST instrument passes a non-pain code through electrodes on the skin surrounding the pain site to the spinal cord and ultimately to the brain. The ST code scrambles the pain code and therefore pain sensation is reduced or eliminated. Data analysis utilizing the Visual Analog Pain Rating Scale (VAS) and the Brief Pain Inventory (BPI) prior to the application of ST and 6 months following the use of ST was conducted and demonstrated significant reduction in pain and in the chronic pain syndrome in people with CRPS.

Introduction

Complex regional pain syndrome (CRPS), formerly reflex sympathetic dystrophy or causalgia, is a chronic systemic disease characterized by severe pain, swelling and changes in the skin. CRPS is expected to worsen over time. It usually impacts the arm or leg and then spreads throughout the body. It has been reported that 92% of patients report a spread of the pain and 35% report whole body symptoms. CRPS is considered to be a multifactorial disorder with the following clinical features: neurogenic inflammation, nociceptive sensitization (e.g. allodynia), vasomotor dysfunction and maladaptive neuroplasticity, generated by an aberrant response to tissue injury. Treatment, to date, is complicated, involving drugs, physical therapy, psychological treatment and neuromodulation (e.g. TENS) and usually unsatisfactory especially if treatment begins late.

CRPS is associated with dysregulation of the CNS and ANS resulting in multiple functional loss, impairment and disability. IASP has proposed dividing CRPS into two types based on the presence of nerve lesion following the injury.

Type I: Formerly RSD. No demonstrable nerve lesion(s).
Type II: Formerly Causalgia. Evidence of obvious nerve damage.

CRPS has been described as one of the most painful disorders experienced above such events as amputation and childbirth. CRPS is considered a neuropathic pain disorder.

Scrambler Therapy

Gate-Control theory has been the dominant theory explaining pain mechanisms. Melzack (1999) has suggested the gate-control theory is more effective in understanding acute and sub-acute pain rather than chronic pain and suggested a central source of pain that develops through the pain neuromatrix. Scrambler Therapy theory although developed independent of the neuromatrix theory, also approaches chronic pain from a central perspective in which an initial sensory source enters the spinal cord from the periphery, activates neurochemical responses and ultimately sends information to the brain that is decoded as pain. Despite surgical correction or natural healing the information sent to the brain for decoding erroneously persists as pain well beyond the expected healing time frame. As this persists entropy increases and the individual is now trapped in an inescapable pain experience that has little hope of improving since corrective information is not being produced by any treatment approach. By providing corrective information through ST (bioelectrical codes) through the periphery (dermatomes) to the dorsal horn of the spinal cord and CNS the new code "tricks" the brain to read a discernable non-pain code as real and generated from self. Through plasticity the brain will then learn to expect and look for the non-pain signal and prefer it thus returning to an improved state of homeostasis (perhaps deactivating the pain neuromatrix proposed by Melzack, 1999).

Evidence of the Validity and Efficacy of Scrambler Therapy

Literature:

In one of the first published investigations of scrambler therapy (ST) Marineo (2003) reported on the treatment of 11 terminal cancer patients suffering from drug-resistant neuropathic pain. He applied ten treatment sessions of ST to these patients and reported that 81.8% of the patients were able to discontinue pain medications and 18.2% were able to reduce their dosage of pain medication. These results were felt to be encouraging and a second investigation was conducted and published in 2003 (Marineo, Spaziani, Sabato & Marotta, 2003) in which 33 patients suffering from drug-resistant chronic neuropathic pain were treated with 10 sessions of ST. The entire sample responded positively to the treatment with significant declines in VAS (Visual Analog Scale) scores. Seventy-two percent of the patients suspended treatment with pain medications while the remaining 28% significantly reduced their dose taken prior to ST.

Sabato, Marineo & Gatti (2005) expanded their population to the treatment of 226 patients with various forms of neuropathic pain (e.g. sciatic and lumbar pain, post-herpetic pain, post-surgical nerve injury pain, pudendal neuropathy, brachial plexus neuropathy and others). They applied only 5 ST treatments of 30 minutes and were able to demonstrate significant improvement with 80% of the sample reporting a better than 50% relief from pain and only 9% with no positive response to the treatment.

More recently several studies have continued to demonstrate efficacy of ST. In a study of 40 cancer patients and 33 non-cancer pain patients VAS scores were compared at the initiation of treatment, after the 10-session treatment and again at 2 weeks following treatment (Ricci et al. 2011). In their sample the average VAS score was 6.2 just prior to treatment. After ten treatment sessions the average VAS was 1.6. Two weeks following treatment the average VAS score was 2.9.

Marineo et al. (2012) conducted a clinical trial with patients randomized to either guideline-based pharmacological treatment or ST. Patients were matched by type of pain (i.e. post-herpetic neuralgia, postsurgical neuropathic pain, and spinal canal stenosis). The VAS score was recorded prior to the initiation of the first treatment and after each of ten treatment sessions. The control group VAS was 8.1 and the ST group 8.0. At one month following the post ST treatment session the ST group VAS score was .7 while the control group was 5.8. At two and three months, the mean VAS scores in the control group were 5.7 and 5.9. The ST group scores were 1.4 and 2. These results clearly suggest that ST is far superior at relieving neuropathic pain than drug management. The mechanisms by which this treatment effect occurs was speculated as to include raising the "gate" threshold for pain at the spinal cord, reducing "wind-up" (central sensitization of the spinal cord and brain that amplifies the abnormal feelings), reducing impulses from the damaged nerve, and reducing psychological maladaptation to pain (Jenson, 2010). The most recent investigation (2012) has demonstrated similar levels of treatment efficacy in the treatment of post-herpetic pain with ST (Smith, Marineo, Coyne and Dodson 2012).

Sparadeo, Kaufman & D'Amato (2012) compared three chronic pain diagnostic groups (Single site spine-based pain, complex regional pain syndrome and multisite chronic pain) utilizing ST and found significant treatment effects enduring 3-6 months following the last treatment.

Sampling and Procedures

This investigation applied ST to 37 consecutive patients entering a chronic pain treatment program with a diagnosis of CRPS (Type I). All patients in this investigation were diagnosed by a physician. A second diagnostic group consisting of 42 patients with varying forms of neuralgia were also followed and comparisons were made with the CRPS group.

Method

Data for this study was collected in the Calmar Pain Relief center in Rhode Island. This center was the first clinic in the U.S. to offer Scrambler Therapy (ST) exclusively to treat chronic pain. All patients were treated according to standardized methods of ST. Patients with psychosis, non-neuropathic pain, neuropathic pain outside of the 2 diagnostic groups stated and patients with acute pain were excluded from this study.

The data was composed of a pre-treatment visual analog measure of pain (VAS) and pre-treatment administration of the Brief Pain Inventory (BPI) and Sickness Impact Profile (SIP). The data was recorded in the medical record. Each treatment session also included a VAS measure at the time of treatment initiation and at the conclusion of the treatment session. This data was also recorded in the medical record. Finally, each patient was contacted at a follow-up period of 6 months following the last ST and the VAS and BPI were re-administered and recorded in the medical record. All of the patients were treated consecutively. Approximately 45% of the total number of patients treated were lost to follow-up. At the time of this study there were over 500 patients of varying neuropathic pain diagnoses treated and 100 patients participated voluntarily in the follow-up process.

An ANOVA was conducted comparing means on the measures between the two diagnostic groups (CRPS and Neuralgia). Wilcoxin Rank Sum Test was conducted across ten ST treatment sessions for the CRPS group.

Paired t-tests were conducted across the specific items from the BPI, the BPI summary score and the VAS (pre-treatment and post-treatment).

Measures

The Brief Pain Inventory (BPI) is a 7-item rating scale from 0-10 in which the patient rates the degree of negative pain effect with 10 the most severe.

The Sickness Impact Profile is a self-report consisting of a series of statements within specific life areas in which the subject either agrees with the statement or leaves it blank. A scoring system allows for composite measures indicating the average level of perceived impact from pain on: Physical functioning, Psychosocial functioning, Work/Recreation and Overall.

The Visual Analog Scale (VAS) is a 10-inch line numbered from 0-10 in which the patient circles the level of pain they are experiencing at that time with 10 the most severe.

Table 1. Mean age and SD for each diagnostic group

Diagnostic Group	N	Mean	S.D.
CRPS	37	47*	14.9
Neuralgia	42	62	18.2

*p<.001 (CRPS patients were significantly younger)

Table 2. Pre & Post-treatment means for each diagnostic group*

BPI + VAS	CRPS-Pre	Neuralgia-Pre	CRPS-Post	Neuralgia-Post
Activities	7.3	7.6	3.1	2.7
Mood	6.1	6.3	2.5	2.4
Ambulate	6.0	6.9	2.9	2.5
Work/Household	6.7	7.5	3.4	2.5
Interpersonal	5.8	6.0	2.3	1.5
Sleep	7.2	6.3	3.3	1.9
Joy	7.4	7.6	3.1	1.9
VAS	7.2	7.0	3.2	3.1

* T-test paired comparisons were all significant at the p<.001 level.

RESULTS

ANOVA results for differences in mean age between diagnostic groups indicated that the CRPS were significantly younger than the Neuralgia group with a mean age of 47 (Table 1). ANOVA results with means comparisons (CRPS vs. Neuralgia) on all dependent variables (BPI and VAS) prior to treatment were non-significant. ANOVA comparing SIP means at the pre-treatment period were significantly higher in the CRPS group indicating a greater percentage of pain impact on three major life dimensions and the overall composite score (Figure 1).

Figure 1. Mean SIP Composite Scores for each diagnostic group

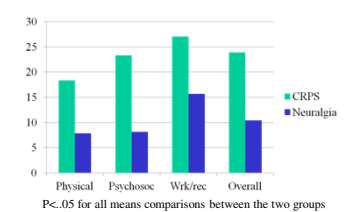
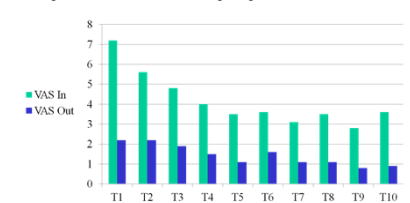


Figure 2. CRPS Pain level at the beginning and end of each ST session (N=37)



Wilcoxin Rank Sum Test indicated that there was a significant treatment effect for each of 10 sessions. (Figure 2). Paired t-tests comparing pre and 6-month post BPI and VAS were all significant with CRPS demonstrating significant improvement when comparing pre-treatment measures to post-treatment measures (Table 2).

ANOVA comparing post-treatment VAS and BPI measures was non-significant suggesting the treatment as equally effective for both groups.

CONCLUSIONS

The availability of effective treatment for CRPS is quite limited. Attempts to manage CRPS through the use of various medications (including opiates) have been a disaster with estimates of over 60% addiction rates. Until now neuromodulation has had limited positive impact and implantable devices are quite expensive. Scrambler Therapy is an innovative form of surface neuromodulation that is based in cybernetic and information theory. Research to date has demonstrated excellent outcomes with pain reduction rates over 75% in most cases. This investigation applied ST to 2 diagnostic groups with neuropathic pain (CRPS and Neuralgia). These patients were treated in the normal course of business in a specialized chronic pain treatment program (Calmar Pain Relief, LLC) and then followed for 6 months after the last treatment. The results were highly significant within and also at follow-up. ST is a low cost and highly effective non-invasive treatment for neuropathic chronic pain syndrome, and in particular CRPS, that not only relieves intractable pain but also eliminates the chronic pain syndrome.