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 $560-655 billion in direct costs and lost productivity. Among these people experiencing chronic pain are those diagnosed with Complex Regional Pain Syndrome (CRPS). This study was designed as an exploratory study to evaluate the efficacy of one-on-one neuromodulation technique to reduce pain in people with CRPS. The gate-control theory of pain is not adequate to fully understand this chronic pain group of patients. A technique that utilizes an electrical stimulus based on 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 uses a non-pain compound electrode on the skin surrounding the patient’s 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 referred to as 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 almost 50% of the whole body syndrome. CRPS is considered to be a multifactorial disorder with the following clinical features: sympathetic inervation, nociceptive sensitization (e.g. algodystrophy), vasomotor dysfunction and maladaptive neuropathic complex 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. JASP 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 autotransplantation and childbirth. CRPS is considered a neuropathic pain disorder.

### Scrambler Therapy

- **Gate-Control theory** has been the dominant theory explaining pain mechanisms. Melzak (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 (peripheral) to the spinal cord and CNS is inescapable pain experience that has little hope of improving since surgical correction or natural healing the information sent to the brain that is decoded as pain.

- **Method**

  **Scrambler Therapy**

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- **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 physical therapist and diagnostic group consisting of 42 patients with varying forms of neuralgia were also followed and compared to make the CRPS group.

### Data Analysis

- **Literature**

  In one of the published investigations of scrambler therapy (ST) among 28 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 (Marino, Spatiani, 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 with the remaining 28% significantly reduced their dose taken prior to ST.

- **Statistical Analysis**

  - **Pre-treatment:**
    - **VAS:**
      - Mean: 7.1
      - SD: 1.4
    - **BPI:**
      - Mean: 6.2
      - SD: 1.9
  - **6 months post-treatment:**
    - **VAS:**
      - Mean: 3.7
      - SD: 1.5
    - **BPI:**
      - Mean: 3.2
      - SD: 1.7

### Conclusions

The availability of effective treatment for CRPS is quite limited. Attempts to manage CRPS through the use of various medications (including opioids) 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 up and reviewed. The results were highly significant and within and at follow-up. ST is a low cost and highly effective non-invasive treatment for chronic neuropathic pain and the patient results reported by the SCRAM group indicate a greater percentage of pain impact on three major life dimensions and the overall composite score (Figure 1).

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**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)**

**Table 1.** Pre & Post-treatment means for each diagnostic group**

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

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**Wileksin Rank Sum Test indicated that there was a significant treatment effect for each of 10 sessions.**

**Paired t-tests comparing pre and 6-month post BPI and VAS were all significant**

**ANOVAs comparing post-treatment measures to post-treatment measures (Table 2).**

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

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**CONCLUSIONS**

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