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CASE SERIES

Scrambler Therapy for Treatment of Chronic Nonmalignant Pain

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ABSTRACT

Aim: The aim of this study is to investigate scrambler therapy as a modality of treatment for chronic pain.

Materials and methods: Four patients with chronic drug-resistant severe pain were treated with scrambler therapy, a new bioengineering-based method for treating pain, especially neuropathic pain. The effectiveness of the treatment was evaluated using numeric rating score (NRS); reduction in amount of pain medications and side effects if any were also noted. Each patient was given 10 cycles (or the number of cycles required for complete pain relief) of 30 minutes duration each, and the above parameters were noted.

Three of the four patients had chronic neuropathic pain, and the fourth patient had somatic (bony) pain. All of them showed more than 80% reduction in their pain scores and reduction in the consumption of pain medications.

Keywords: Disk prolapse, Neuropathic pain, Numeric rating scale, Scrambler therapy.

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INTRODUCTION

Neuropathic pain is common, chronic, disabling, and often difficult to effectively treat.[1] Common types of neuropathic pain include postsurgical pain, postherpetic neuralgia, spinal cord stenosis (SCS) (also known as narrow canal syndrome), and chemotherapy-induced peripheral neuropathy.[2] Although conventional treatments, such as opioids, neuroleptics, and other drugs help, all have side effects and limited effectiveness.[3]

Scrambler therapy is a novel approach to control pain that attempts to relieve pain by providing "nonpain" information via cutaneous nerves to block the effect of pain information. Scrambler therapy synthesizes 16 different types of nerve action potentials similar to endogenous ones, assembles them into sequences, and uses algorithms to determine a patient-specific cutaneous electrostimulation to reduce pain. Scrambler therapy has relieved refractory chronic pain in uncontrolled clinical trials. In the pilot trial, 11 cancer patients with abdominal pain received 10 daily 1-hour treatment sessions.[4] Pain was reduced from 8.6 to 2.3, on a numeric rating scale from 0 to 10, after the first treatment and to <0.5 ($p < 0.0001$) at the end of 10 sessions. In the second trial, 226 patients with neuropathic pain, including failed back surgery pain, brachial plexus neuropathy, and others, were treated.[5] Eighty percent of patients had greater than 50% pain relief. Smith et al[6] treated 16 patients with refractory chemotherapy-induced neuropathic pain with 10 daily hour-long sessions to the painful areas. Pain scores were reduced by 58% from the start of treatment to the end. No toxicity has been observed in any trial.

This is a pilot study being done for the first time in India to evaluate the effectiveness of scrambler therapy for chronic pain.

MATERIALS AND METHODS

The therapy was provided in the Department of Onco-Anaesthesia and Palliative Medicine, Indian Rotary Cancer Hospital, All India Institute of Medical Sciences.

The current report is of patients with chronic pain of varying etiologies. The diagnostic groups in this report included people with multiple site spine-based pain and complex medical histories (arthritic pain, diabetic neuropathy). These patients had either drug/alternate therapy non-responsive pain or sought a therapy with lesser side effect profile and better efficacy than their existing treatment.

Patients were not eligible for the trial if they were pregnant or if they had an implantable drug delivery system, metal implants (pacemakers, automatic defibrillators, aneurysm clips, *vena cava* clips, and skull plates), history of epilepsy/brain metastasis/traumatic brain injury/open sores or active skin infection which would interfere with electrode application or had any other medical conditions which might interfere with the study.

Scrambler Therapy

On the initial day of treatment, the most symptomatic area of neuropathic pain was determined. Electrodes, similar to electrocardiogram patches, were placed adjacent

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to the symptomatic site. Once a pair of electrodes was positioned appropriately, the device was turned on, and the electrode intensity was increased to the maximally tolerated intensity. If the patient did not have improvement in symptoms, the device was turned off, and electrodes were removed and repositioned. Once proper initial electrode placement was achieved, resulting in a decrease in symptoms, additional electrode sets were placed to further encompass the symptomatic area. Up to five channels or sets of electrodes could be used during treatment. Each patient received daily sessions for up to 10 consecutive days, Monday to Friday, for 30 minutes. Patients had the option to stop treatment for lack of significant benefit. Treatments were also stopped prior to 10 days if all the pain and tingling resolved.

About the Machine

Calmare MC-5A was the pain therapy device used in our study. The electrical charge used in scrambler therapy is low and has been approved as safe by the Food and Drug Administration. At the highest setting, "70" on the dial from 10 to 70, the amperage (A) is 3.50 to 5.50 mA, with a voltage range of 6.5 to 12.5 V. We used a setting of "40 to 50" for our patients based on their response.

Study Endpoints

The primary measure of symptoms was made using DN-4 neuropathy symptom questionnaire (Table 1), which included questions assessing the presence of burning, numbness, tingling, pain, paresthesias, or hypoesthesia. Single-item visual analog scales were demonstrated to be a valid and reliable measure of quality of life and symptoms in cancer patients.[7] A similar numeric analog question asking about combined numbness, tingling, and pain was used daily prior to each treatment (Graph 1).

RESULTS

Case 1

A 74-year-old female patient presented with complaint of low backache radiating to the right leg. She was diagnosed with disk prolapse in 1998 on magnetic resonance imaging (MRI), which was managed conservatively. She is also a known case of type 2 diabetes mellitus since 44 years, well controlled on insulin, and also has history of ischemic cerebrovascular accident twice in 2002 and 2013.

The patient was already on physiotherapy exercises and lumbar traction, but there was no symptomatic relief with the same. She was also on Tab Pregabalin 75 mg BD and Tab Paracetamol 1 gm QID.

The patient was started on scrambler therapy on September 3, 2015. She was given 10 sittings each of 30 minutes duration. Five electrodes were used, two at the L4–5 spine and three on the right leg. The patient was symptomatically relieved after 10 sittings. She discontinued the oral medications after the third sitting.

Case 2

A 50-year-old male patient presented with complaint of pain in the neck radiating to both shoulders and feeling of numbness in the left middle finger. He was diagnosed in 1999 with C4–C7 disk prolapse and underwent discectomy and artificial disk placement at C4–5 and C5–6 level in 2013. He also complained of backache of unknown etiology. At the time of presentation, the patient was not on any medications for the same.

Scrambler therapy was started for this patient in September 2015. Five electrodes were used: two each in the cervical region around C4–7, two in the back (L4–5), and one on the left shoulder. The patient had complete pain relief in just five sittings.

Case 3

A 55-year-old female patient presented with complaint of low backache radiating to the right leg. On MRI studies, the patient was diagnosed to have L4–5 disk prolapse. The patient was taking Tab Flexon TDS and Tab Pregabalin 75 mg BD.

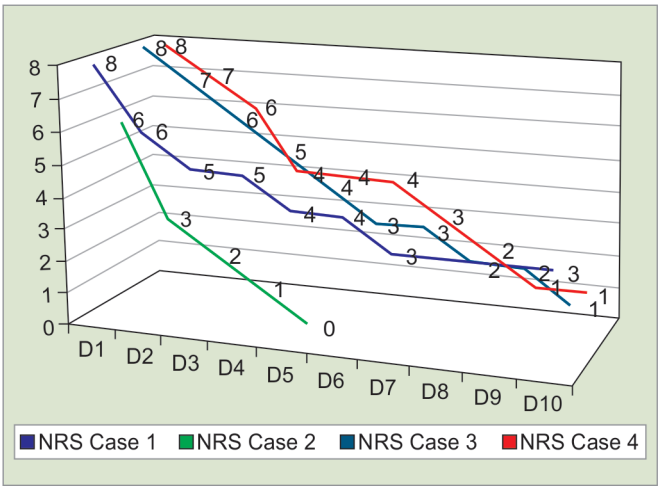
The patient had nearly complete pain relief by the end of 10 sittings. Of the five electrodes, two electrodes were placed in L4–5 spinous processes and three were placed on the right leg. She also stopped the oral medications after three sittings.

Case 4

A 55-year-old female patient presented with complaint of pain in both knees and early morning stiffness of both the knee joints. Radiological investigations suggested

Table 1: Evaluation of the principal complaints using DN-4 neuropathic pain questionnaire for first three cases

	Burning	*Painful sensation of cold*	*Electric shocks*	*Tingling*	*Pins and needles*	*Numbness*	*Itching*	*Hypoesthesia to touch*	*Hypoesthesia to prick*	*Pain provoked by brushing*
C1	–	–	+	+	+	+	–	+	+	–
C2	–	–	+	+	+	+	–	+	+	–
C3	–	–	+	+	+	–	–	–	–	+



Graph 1: Graphical depiction of the overall NRS score of the patients with scrambler therapy with each sitting

reduced joint space and presence of osteophytes in both the joints. She was taking Tab Paracetamol 1 gm B.D., which was reduced to 500 mg as and when required.

DISCUSSION

All the four patients in this case report had large and persistent pain relief, and two patients could totally stop their pain medication after the therapy. The dial setting was kept at "40–50" for our patients.

The mechanism of action of scrambler therapy is not completely clear; yet, however, some observations were made, which were similar to the findings in previous studies by Marineo et al.[8]

First, scrambler therapy gives new "nonpain" information such that patients report new sensations in the pain area (pressure, itching, "bee sting" sensations, and a flow of impulses). Second, it is not simple C-fiber electrical stimulation, which would produce pain. Third, scrambler therapy is not producing paresthesias because the patient does not feel numbness and can still feel other noxious stimuli. Fourth, scrambler therapy analgesia occurs quickly, suggesting that the receptors are transmitting the "nonpain" information. Fifth, the sustained pain relief for days or months, which was verified by a telephonic call in our cases, suggests either resetting of calcium channels or remodulation of the pain system's response.

Another point which was noted was that the rapidity of response to therapy was dependent on the initial pain scores. Finally, the patient feels the sensation throughout the dermatome, not just under the electrode patch, suggesting the spread of "nonpain" information along the lines of nerve transmission. Clearly, more study is needed to define the effect and the mechanisms.

Further studies are required to determine the effectiveness of the therapy in a more diverse subgroups of neuropathic pain, whether the most effective technique of pain relief is to place the electrodes at the appropriate dermatomal level, adjacent to the involved dermatomal level,[8] or at the site of maximum tenderness[9] and comparison using a control arm to rule out placebo effect and long-term effects of scrambler therapy.

CONCLUSION

The effectiveness of treatment of chronic pain has been poor. Professionals working in the chronic pain clinic fail to reduce pain or improve quality of life for the individuals suffering from chronic pain.[10] The interventions with the most empirical support for the treatment of chronic pain are psychological[11] (e.g., cognitive behavior therapy). The use of epidural steroid injections is of questionable utility with very poor results in controlled studies.[12] Despite the lack of efficacy of epidural steroid injections, they are commonly used in pain clinics, and they are quite costly. Attempts to manage pain through the use of various medications (including opiates) have been poor, with estimates of over 50% addiction rates,[13] and pain relief is not always satisfactory.

This pilot study is the first of its kind in the Indian population, and no side effects were reported in any of the cases. Scrambler therapy is a promising technique that provides effective pain relief and reduction in the requirement of oral medications and is cost effective.

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