

Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial

Giuseppe Marineo PhD^a, Vittorio Iorno MD^b, Cristiano Gandini MD^b, Vincenzo Moschini MD^b and Thomas J. Smith MD^c

^a Delta Research & Development, Centro Ricerche Bioingegneria Medica, University of Rome "Tor Vergata," Rome, Italy

^b Centro di Medicina del Dolore "Mario Tiengo", IRCCS Fondazione Ospedale Maggiore Policlinico, Mangiagalli and Regina Elena, Milan, Italy

^c Division of Hematology/Oncology and Palliative Care, Massey Cancer Center, Virginia Commonwealth University, Richmond, Virginia, USA

Abstract

Context

Neuropathic pain is common, disabling, and often difficult to treat.

Objectives

To compare guideline-based drug management with Scrambler therapy, a patient-specific electrocutaneous nerve stimulation device.

Methods

A clinical trial with patients randomized to either guideline-based pharmacological treatment or Scrambler therapy for a cycle of 10 daily sessions was performed. Patients were matched by type of pain including postsurgical neuropathic pain, postherpetic neuralgia, or spinal canal stenosis. Primary outcome was change in visual analog scale (VAS) pain scores at one month; secondary outcomes included VAS pain scores at two and three months, pain medication use, and allodynia.

Results

Fifty-two patients were randomized. The mean VAS pain score before treatment was 8.1 points (control) and 8.0 points (Scrambler). At one month, the mean VAS score was reduced from 8.1 to 5.8 (-28%) in the control group, and from 8 to 0.7 points (-91%) in the Scrambler group ($P < 0.0001$). At two and three months, the mean pain scores in the control group were 5.7 and 5.9 points, respectively, and 1.4 and 2 points in the Scrambler group, respectively ($P < 0.0001$). More relapses were seen in polyradicular pain than monoradicular pain, but retreatment and maintenance therapy gave relief. No adverse effects were observed.

Conclusion

In this pilot randomized trial, Scrambler therapy appeared to relieve chronic neuropathic pain better than guideline-based drug management.