A Neuromodulation Technique that Regenerates Nerves Destroyed by Neuropathy

Peter M. Carney M.D. FAANS; Robert R H Odell, Jr M.D., PhD.; Steven Kreisher PA-C; Lisa A. Galloway M.D.

Peter M. Carney, M.D., F.A.A.NS. • 244 Waterfall Drive • Elkhart, IN. 46516
Phone: 574: 389-7737 • Fax: 574: 389-3196 • e-mail: pmcegh@aol.com

INTRODUCTION: "Neuromodulation is a therapeutic alteration of activity either through stimulation or medication." Peripheral Neuropathy (PN) affects an estimated 23 million Americans1 and has been described as a neurodegenerative disease which causes complex damage to nerves and impairs their regeneration. As such it offers an ideal target for utilizing Neuromodulation techniques.

At present numerous "guidelines"2,3 have concluded that pharmaceuticals offer the best treatment option for PN even though "the treatments available for PN do not relieve pain completely in the majority of patients and most have adverse effects"3,4. Indeed, randomized, placebo controlled trials have shown that at 600mg/day pregabalin helps 39% of patients reduce their pain by 50% but at least 38% of patients had one or more adverse side effects5. To overcome these limitations some have suggested that "interventions aimed at nerve regeneration may need to be employed."4 Beginning with the Nobel Laureate, Erwin Schrodinger, the developing field of quantum biology has begun to help us find ways to regenerate nerves.

The principles of quantum mechanics underlie a very sophisticated electronic signaling technique (EST) which uses computer controlled, exogenously delivered specific parameter electroanalgesia6. Combined with the injections of local anesthetics and called Combined Electrochemical Therapy (CET)7 it produces clinical results significantly more effective and safer than conventional pharmacological methods.8,9,10

CLINICAL:

The average patient dropped their VAS score by 5.6 VAS points. 34 patients (83%) decreased their VAS by at least 50%. 37 patients (90%) decreased their VAS by at least 30%. 41 patients with an avg Pre CET VAS 7.5 (2-10), Post CET VAS 1.9, (0-8), 75% change.

The Berg Balance Test showed 73% of Patients with High to Moderate risk of falling improved to low risk.

Ulceration Risk: 10 of 11 patients at risk for feet ulceration improved to no risk.

Neuropathy Functioning Index (NFI): 10 of 11 patients improved their NFI by an average of 52% per patient.

CONCLUSION: CLINICALLY: In this study the average patient reduced their pain by 5.6 VAS points and 34 of 41 patients had a 50% or higher reduction in their pain score (83%). None had any adverse side effects. The 82 patients who received 600 mg/day of pregabalin in a randomized placebo controlled double blind study reduced their average VAS score by 2.4 points. 39% reduced their VAS by 50% or more and 38% had at least one adverse side effect. Thus as compared to the "gold standard" of pharmaceutical treatment for PN, clinically CET reduces the VAS score 133% better than pregabalin (P = >0.00006). The 83% of CET patients who reduced their pain by 50% did 113% better than the 39% of patients who reduced their pain by 50% after receiving pregabalin (P = >0.003). As compared to the 38% of pregabalin treated patients who had at least one adverse side effect, none of the patients receiving CET had any adverse side effects.

ANATOMICALLY: Thirty of forty-one patients (73%) had some regrowth in nerves damaged or destroyed by neuropathy with twenty five patients (61%) having at least a 25% increase in their nerve fibers and one patient going from having no fibers on her original biopsy to having a normal number six months after finishing her treatment. These biopsy pictures show that combining electromagnetic stimulation with the administration of local anesthesia does regenerate nerves.

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METHODS: Forty-one adults with PN consented to be treated by this technique at three different clinics. They all had CET delivered to each foot or leg twice a week for up to 25 treatments. Anatomically each patient had Epidermal Nerve Fiber Density (ENFD) biopsies done at 2 to 4 sites prior to starting treatment and 3 to 10 months after treatment.Clinically, all patients during their treatment had their highest VAS score recorded and compared with their VAS at the end of treatment. In addition, some patients had Berg Balance tests done before and after therapy, some had their risk of developing ulcers as determined by monofilament testing checked, and some had their neuropathy functioning index checked before and after treatment.

RESULTS: ANATOMIC: Twenty-four males (59%) and 17 females (41%) with an average age of 68.5 (48-89) had a total of 116 biopsy sites done at the proximal thigh, calf (unilaterally or bilaterally) and for some at the foot (an average of 2.8 biopsy sites per patient).

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41 patients had a total of 116 Biopsy Sites, avg. 2.8/pt. 47 Sites were positive, 40.5%. Average Pre CET ENFD was 3.0 fibers/mm, average Post CET ENFD was 4.5 fibers/mm, or a 50% change.

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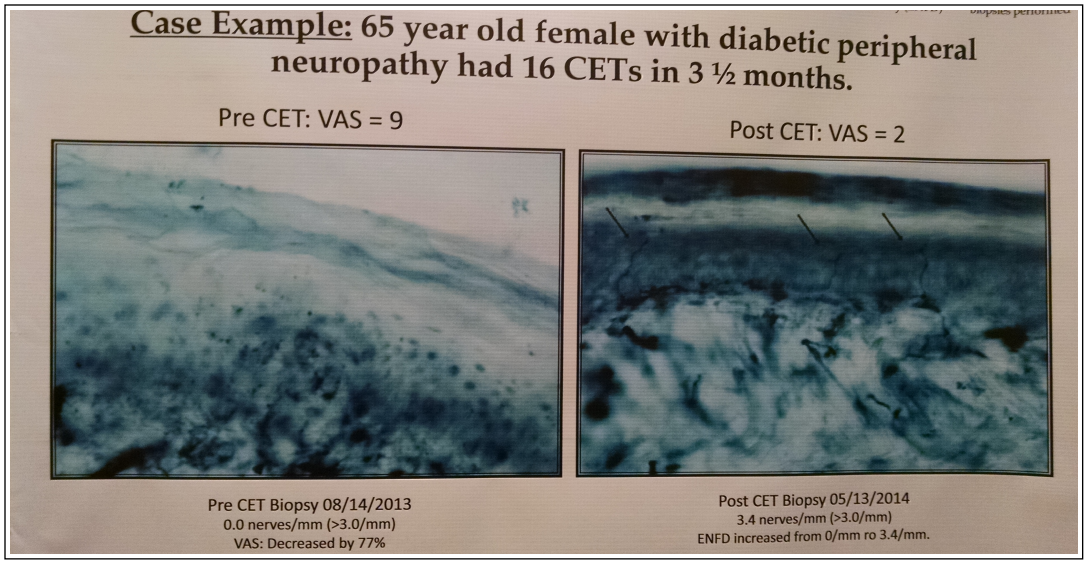
25 Patients, 61%, increased their ENFD by greater than 25%, 29 to >1033%. 5 patients, 12%, increased their ENFD by 1 to 25%, 6% to 21%. 11 Patients, 27%, had no growth.

ADVERSE SIDE EFFECTS: None



Thus, the clear and convincing pictures coupled with the impressive clinical results raise two important questions:

1.) When will CET be available to help the millions1 who suffer daily from PN?

2.) How does combining electromagnetic energy fields with injections of local anesthetics cause nerves to regenerate?

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