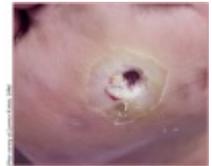


Can Combined Electrochemical Treatment Have An Impact For Diabetic Peripheral Neuropathy?

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In the United States and most developed countries, medical care focuses more on the treatment of acute disease than chronic diseases, even though chronic disease processes consume a large proportion of healthcare resources. Currently, we treat peripheral neuropathy, caused by diabetes and other processes, by controlling its symptoms and not healing damaged nerves. A new technique utilizing the principles of quantum mechanics allows damaged nerves and tissues to heal without the side effects associated with pharmaceutical agents.

Peripheral neuropathy occurs as a component of several common and many rare diseases. It is heterogeneous in etiology, diverse in pathology and varied in severity. Peripheral neuropathy is often undervalued as a significant problem worldwide.



Neuropathy due to diabetes and other causes is rampant in the U.S. population (more than 8 percent by some estimates) and projections suggest that it will become worse.¹ Neuropathy, at least subclinically, is often the first sign of diabetes. Symptoms of other end organ damage may be less perceivable. Morbidity associated with neuropathy from diabetes, chemotherapy and other diseases is a major reason why patients seek medical care and is a huge cost to third-party payers in the U.S. and around the world. This nerve disease affects millions of people worldwide by causing multiple foot, ankle, hand, wrist and other muscular and skeletal disorders.

How Much Does Diabetic Peripheral Neuropathy Cost The Healthcare System?

The costs to the world economy are staggering. In the U.S. alone, the annual total direct medical and treatment costs of diabetes were an estimated \$44 billion in 1997, representing 5.8 percent of total personal healthcare expenditures during that year.¹ When it comes to diabetic peripheral neuropathy and its complications, management is resource intensive and long-term, accounting for a large proportion of this total expenditure. In 2001, the total annual cost of diabetic peripheral neuropathy and its complications in the U.S. was estimated to be between \$4.6 and \$13.7 billion.

Up to 27 percent of the direct medical cost of diabetes may be attributed to diabetic peripheral neuropathy.¹ These staggering figures only cover the annual cost of diabetic peripheral neuropathy, which is believed to represent only 35 percent of the prevalence of overall peripheral neuropathy. Sixty-five percent of all the causes of peripheral neuropathy are not related to diabetes.

Taken together, not only can diabetic and other types of peripheral neuropathy lead to tremendous debilitating complications (such as amputations, pain, numbness, loss of balance, sleep and strength, quality and length of life; and polypharmacy use), but they also account for significant overall morbidity and increased healthcare costs. Some studies have shown that the costs of caring for patients with diabetic neuropathy can be \$7,000 more per year than caring for the patient with diabetes without neuropathy.² We believe most of this cost goes toward symptom management, not pathophysiology reversal and nerve regrowth.

Surveying The Treatment Options For Peripheral Neuropathy

Diabetic neuropathy develops well before the patient has any symptoms.¹ The sooner treatment can begin, the greater the chances of reversing the symptoms. This is an endopathic disease of the microvascular circulation caused by dysfunctional glucose metabolism, having direct effects on the vessels feeding the nerves as well as the nerves themselves. Pain signals in turn trigger secondary peripheral and central hyperalgesia, which enhances the body's response to the microvascular insult. Ephaptic transmission can generate painful dysesthesias and allow numbness to coexist with pain at the same locations. On a local level, microinflammation and edema around the nerves also contribute to neuropathy and diseases such as carpal tunnel syndrome and neuromas.

In regard to possible modalities for patients with peripheral neuropathy, treatments include modifying risk factors by lifestyle changes; vitamins and supplements; physical medicine; topical medicinal treatments; prescribed oral medications; transcutaneous electrical nerve stimulation (TENS) units; monochromatic infrared light energy (MIRE, Anodyne Therapy); Anodyne (Anodyne Therapy); Advanced MicroVas II (MicroVas); and surgery.³⁻⁶

The most common approach is oral medications that only mask the symptoms. According to Berger and colleagues, 53.9 percent of patients with diabetic peripheral neuropathy receive treatment with opioids, 39.7 percent take anti-inflammatory drugs, 21.1 percent use serotonin selective reuptake inhibitors (SSRI), 11.3 percent take tricyclic inhibitors and 11.1 percent take anticonvulsants (Neurontin and Lyrica).⁷ The "gold standard" in treating peripheral neuropathy, pregabalin (Lyrica, Pfizer), helps 39 percent of patients achieve a 50 percent reduction in their discomfort and pain, but causes at least 38 percent to have complications.⁸ These medications have drawbacks and major adverse effects.

Pertinent Insights On An Emerging Treatment For Peripheral Neuropathy

An innovative and effective treatment has been established for diabetic and other peripheral neuropathies. Combined electrochemical treatment incorporates two well-established procedures into a protocol that is showing great promise as a safe and effective treatment for all neuropathies.⁹⁻¹¹ The combined electrochemical treatment consists of an ankle block that one performs with a local anesthetic and electronic signal treatment, which clinicians deliver through a unique sophisticated electronic signaling generator.

One would perform the peripheral nerve injections with a low volume and concentration of local anesthetic. Bupivacaine fixes to the tissues less rapidly so more time is available for the iontophoresis of marcaine into the tissues by the electronic signal treatment. One would perform the blocks aseptically and no infections have reportedly occurred to date in thousands of injections.⁹⁻¹¹

Electronic signal treatment utilizes computer-controlled, exogenously delivered specific parameter electronic cell signals using both varied amplitudes (AM) and frequencies (FM) of electronic signals. This digitally produced electronic sinusoidal alternating current with associated harmonics produces scientifically documented and/or theoretical physiological effects when one applies them to the human body. The electronic signal treatment medical device uses sophisticated communications technology to produce and deliver higher frequency signal energy in a continually varying sequential and random pattern via specialty electrodes. This alternation of sequential and random electronic signal delivery eliminates neuron accommodation. The advanced electronics that produce these signals were not possible even 10 years ago.⁹

Researchers have described the mechanisms of action for combined electrochemical treatment. Basic science and clinical evidence support that combined electrochemical treatment blocks pain signals in several ways, increases blood flow, has a profound anti-inflammatory action and activates intracellular cyclic adenosine monophosphate (cAMP).⁹⁻¹¹

A Closer Look At The Authors' Treatment Outcomes

The concept of combined electrochemical treatment formally debuted in 2008 at the annual International Spine Intervention Society conference. We have used this treatment for over five years.

Diabetic peripheral neuropathy and peripheral neuropathy patients have shown marked symptom reduction and motor function improvement with the application of combined electrochemical treatment.^{10,11} The goals of therapy for diabetic peripheral neuropathy and other neuropathies during the treatment protocol for combined electrochemical treatment are to reduce neuropathic symptoms; reverse pain, paresthesias, dysesthesias, allodynia and numbness; increase strength and balance; and improve quality of life.

Clinically, the most improvement in symptomatology has occurred with patients treated between 10 and 16 weeks.^{10,11} The treatment course varies depending on the severity of the patient's neuropathy and adherence with the treatment regimen. Eighty percent of patients with neuropathic symptoms experience benefits. In some patients, improvement of positive and negative symptoms approaches 100 percent.¹¹

Long-term goals — decreased use of medications, improvement of balance, sleep, overall function, and quality of life — have occurred in a significant plurality of patients with the combined electrochemical treatment. A retrospective study from our clinic showed that over 51 percent of patients were maintaining symptom improvement.¹² Longer-term goals — the prevention of infections and amputations — especially in patients with diabetes, have profound

implications in the ability to save precious healthcare resources.

Thousands of patients have had combined electrochemical treatment around the country. The results show improvement in motor and sensory nerve function that continues to improve even after treatment has stopped. For a subgroup that has had follow-up for as long as five years, clinical improvement continues.¹² Furthermore, changes in epidermal nerve fiber density suggest that nerve regeneration is really occurring.

In Conclusion

The clinical experiences of multiple physicians and podiatrists have shown that the application of combined electrochemical treatment favorably influences the peripheral vasculature and promotes nerve cell regeneration.¹⁰⁻¹³ Long-term results of combined electrochemical treatment have led to little or no return of neuropathy symptoms. As the patients continue to improve, they are better able to exercise, maintain weight loss and control their blood sugar.

Using the principles of physics rather than pharmacology to treat chronic disease represents a paradigm shift. This approach can pave the way for true healthcare reform, in which the scientific application of energy medicine can reverse symptoms and spur true healing. We believe these outcomes will significantly reduce healthcare costs.

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