

Diabetes Watch:

Waveform Electrostimulation: Can It Be Another Option For Painful Peripheral Neuropathy?

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According to the Centers for Disease Control and Prevention (CDC), approximately 7 percent of the population in the United States has diabetes mellitus. Approximately 30 percent of patients with diabetes over the age of 40 have some kind of impaired sensation of the foot. Sensorimotor neuropathy is the primary risk factor for developing a diabetic foot ulcer, which leads to 85 percent of diabetic lower extremity amputations.¹

Sensory neuropathy causes paresthesia and loss of protective sensation, which can lead to ulcerations and lower extremity amputations. Motor neuropathy causes imbalance, leading to injuries and fractures. Some of these injuries and/or fractures may force the patient to lose his or her independence. Autonomic neuropathy can lead to skin ischemia and Charcot events.

Overall, peripheral neuropathy decreases the quality and length of life for our patients. This nerve disease affects millions of Americans and can cause multiple foot and ankle disorders.

In addition to encouraging patients with peripheral neuropathy to modify risk factors, physicians have tried a variety of treatment options ranging from supplements and topical treatments to transcutaneous electrical nerve stimulation (TENS) units and monochromatic infrared light energy (MIRE). Historically, however, non-invasive treatment options have only shown mild to moderate success. Most of these options treat the symptoms but fail to treat the disease.

While there are a variety of oral medications, there may be concerns about possible side effects and/or polypharmacy issues. Surgical nerve decompression remains controversial. When it comes to addressing the symptoms of peripheral neuropathy, we may want to consider whether waveform electrostimulation has an emerging role within our armamentarium.

Weighing The Pros And Cons Of Medications For Diabetic Peripheral Neuropathy

In regard to patients with diabetic peripheral neuropathy (DPN), the most common treatment is oral medication. According to Berger, 53.9 percent of patients with DPN were treated with opioids; 39.7 percent with antiinflammatory drugs, 21.1 percent with serotonin selective reuptake inhibitors (SSRI) such as duloxetine (Cymbalta, Eli Lilly); 11.3 percent with tricyclic inhibitors (TCAs) such as nortriptyline; and 11.1 percent with anticonvulsants such as gabapentin (Neurontin, Pfizer) and pregabalin (Lyrica, Pfizer).²

Despite the cause of the peripheral neuropathy, most physicians treat their patients with the same treatment modalities as those they would use for DPN. A study of approximately 200 patients with DPN utilizing TCAs noted only a modest improvement of symptoms versus placebo.³ When comparing TCA medications versus SSRIs, the authors of another study stated that TCAs were less tolerated but more effective than SSRIs.⁴

Cohen and Susanne performed a study utilizing ibuprofen (600 mg four times daily) and sulindac (Clinoril) (200 mg twice daily). In this study, 18 patients with DPN demonstrated significant statistical reduction in paresthesias. However, using this type of medication has its drawbacks. The risk of renal impairment and gastrointestinal bleeding, in patients with diabetes as well as healthy patients, is well documented with long-term use of non-steroidal antiinflammatories.⁵

Tramadol (Ultram) tends to be a common choice for treating DPN due to its dual action of analgesic and serotonergic properties. A study of 131 patients with DPN demonstrated that tramadol facilitated a significant reduction in pain in comparison with the placebo.⁶⁻⁸ Researchers also have shown that opioid analgesics provide moderate relief of diabetic sensorimotor neuropathy. Adverse effects could include constipation, nausea, sedation and physical dependence.⁸

Finally, while newer drugs such as duloxetine and pregabalin offer safe and effective modalities to decrease the symptoms of painful DPN, they do not reverse nerve damage.^{9,10}

Is Diabetic Nerve Decompression A Viable Treatment Modality?

Another approach to counteract DPN is surgical nerve decompression. In *Podiatry Today*, Barrett discussed the success of decompressing affected nerves.¹¹ Mahoney reported on performing 200 nerve decompression procedures for patients with diabetes and reportedly had an overall success rate of 88 percent.¹²

However, in a 2003 *Podiatry Today* roundtable discussion, Boulton denounces surgical decompression for diabetic peripheral sensory motor neuropathy, emphasizing that this type of neuropathy is not an entrapment neuropathy.¹³ DeHeer points out that the research on surgical decompression has largely been performed by affiliates of the same institute.¹¹

Can Non-Invasive Devices Have An Impact?

Anodyne[®] (Anodyne Therapy) is one of the first non-invasive devices introduced to the market for the treatment of peripheral neuropathy. This FDA-approved device uses monochromatic infrared light energy (MIRE) to increase circulation and decrease pain. In Leonard's study, results showed a decrease in pain for patients with DPN.¹⁴ Recently, Lavery stated that the study performed by Leonard, et al., lacked statistical quality. Lavery also claims the intent to treat strongly influenced the studies by not showing negative results from the patients involved in the studies.¹⁵ Currently, Medicare and other insurances companies do not reimburse for this kind of therapy.

Recently, another device has been introduced into the market. MicroVas[®] (by neuroVasix) is also a non-invasive, FDA-approved device, which utilizes a magnetic waveform to increase blood flow and oxygenation in the area. A preliminary report conducted by Harkless, et al., revealed a lasting reduction in pain and increased sensation of the lower extremities in a study of 20 patients with diabetes.¹⁶

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