treating peripheral neuropathy

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abstract: Peripheral neuropathy (PN) is a serious problem affecting more than 22 million people in the United States, according to The Pacific Chapter of the Neuropathy Association. One in 5 Americans will be diagnosed with this condition during their lifetime, including up to 60% of people with diabetes. Currently there is no cure for neuropathy. Treatment options are quite minimal, geared towards relieving symptoms with medications, but often no treatment of any kind is offered to patients. This study is a retrospective review of 48 charts of patients treated for PN from January 2008 through June 2010 at the Integrative Center for Healing in Cincinnati, Ohio. Treatment of neuropathy used high volt pulsed current (HVPC) electrical stimulation (MicroVas, MTI, Tulsa, OK), with a secondary therapy of stopping statin medication. Symptoms evaluated were pain, numbness, and condition of a wound, if present. With an average of 23 treatments, a statistically significant 83% of patients had improvement in at least 1 symptom. This warrants further study in treatment of neuropathy with HVPC electrical stimulation and/or stopping statin therapy.

key words: peripheral neuropathy, electrical stimulation
KEYPOINTS
• More than 60% of patients with diabetes mellitus will eventually develop neuropathy.³
• While there is much published data on treatment of PN, there are limited studies on any form of pulsed electromagnetic field energy used to treat this condition.
• This retrospective study evaluated the success of the treatment modalities for PN performed in the Integrative Center for Healing, Cincinnati, OH.

ability to live safely on their own may be endangered, resulting in difficult and potentially costly choices for patients and their families.² Medications currently used in treatment include antiepileptics, antidepressants, neuro-modulators, and medications to case pain. These measures have widely varying results in relief of symptoms.⁶⁻¹⁰ Limited attempts at surgical intervention have achieved modest success.¹¹,¹² Other interventions, such as hyperbaric oxygen, massage, acupuncture, and heat/cold therapy, have also yielded only limited success.¹³,¹⁴ Often, a person with neuropathy is told they simply must “learn to live with it.” A reliable therapy for this common condition would be highly desirable.

While there is much published data on treatment of PN, there are limited studies on any form of pulsed electromagnetic field (EMF) energy used to treat this condition. A PubMed search using “pulsed EMF” and “neuropathy” as search terms found 4 published articles. One study¹⁵ did not find benefit. A pilot study with 24 people found unexpected short-term analgesic effects in more than 50% of patients by treating their feet with pulsed EMF.¹⁶ Another study of 121 patients with diabetic polyneuropathy found improvement of clinical symptoms, especially in the initial stages of neuropathy and in patients with diabetes, for up to 10 years.¹⁷ A study in the Ukraine of 12 patients with diabetic polyneuropathy found clinical improvement confirmed by decreased neurological deficit, increased nerve conduction velocity, and increased muscle compound action potentials.¹⁸ A summary of available data indicates that pulsed EMF therapies have beneficial and protective neurological effects.

The clinic in this study specializes in wound care and limb salvage and treats a large number of patients with PN. Patients are either treated specifically for the pain and numbness of their neuropathy, or their neuropathy is treated as an adjunct to their wound care. The hypothesis and practice in this clinic is that treatment of neuropathy with high volt pulsed current (HVPC) is a beneficial adjunctive therapy that could help with wound healing. According to Sussman and Byl,¹⁹ there are 4 types of electrical stimulation to consider: alternating current, direct current, TENS, and HVPC. Their findings are that HVPC is especially beneficial for wound healing.¹⁹ An HVPC electrical stimulation therapy (MicroVas, MTI, Tulsa, OK) has been used in the study clinic since 2002, with excellent results, and a previously estimated success rate of almost 90% with neuropathy, based on reported decreased pain and improved sensation; thus, this was the primary modality studied.

A second independent variable selected in this study was the discontinuation of statin medication if the patient was taking one. The clinical experience in the study facility is that virtually all patients taking statins see improvement in pain and exercise intolerance after stopping statins. This correlates well with the finding by Gaist et al⁰ of increased risk of neuropathy with statins. As such, stopping statin medication is a standard therapeutic procedure in this clinic for patients with neuropathy; thus, it was a second independent variable explored in this study.

This is a retrospective study to evaluate the success of the treatment modalities for PN performed in the Integrative Center for Healing, Cincinnati, OH. Success of treatment is defined as improvement or resolution of symptoms and reversal or improvement of neuropathy by objective testing.

Material and Methods

Institutional review board approval from the TriHealth Hatton Research Institute, Cincinnati, OH, was obtained prior to initiation of the study. A retrospective chart review was performed for all patients treated for PN at the Integrative Center for Healing, Cincinnati, OH from January 2008 through June 2010. Patients were excluded from the study if they did not have a diagnosis of neuropathy, had fewer than 3 treatments, or refused treatment for neuropathy. A total of 48 charts were accepted for review. All charts were reviewed by a specially trained nurse or assistant and data recorded on case record forms (CRF). Each patient was given a unique identification number with personal information removed to maintain confidentiality. Analysis of data was performed using statistical software (Stata Data Analysis and Statistical Software, College Station, TX). Descriptive statistics including mean, median, frequencies, and percentages were calculated, and Student’s t test was performed, to compare differences between groups. The treatment modalities evaluated...
were treatment with HVPC electrical stimulation and stopping statin therapy.

These 2 modalities were used consistently in the treatment of neuropathy in the study clinic. The use of HVPC electrical stimulation was the primary treatment, with other used according to patient need, consent, and preference. All 48 patients in this study were treated with HVPC electrical stimulation. Stopping statins was an option only for those patients who were on a statin when treatment started. No patients in this study stopped statins only without receiving HVPC electrical stimulation treatment. At the beginning of the study, 19 of 48 patients were taking statins and had the opportunity to stop. Of these, 13 stopped taking the statins after receiving instruction on the risks and benefits of that course; in some cases, the author spoke with the patient’s cardiologist to gain agreement.

The HVPC electrical stimulation treatment consisted of weekly 45-minute treatments, with the intensity varied at each treatment according to patient tolerance. Intensity ranged from 1 (lowest voltage) -10 (highest voltage) and was adjusted by the operator for each treatment, often during treatment. The goal of treatment is to use the highest level tolerated by the patient. Intensity settings, while recorded, were not tracked for this study, only the number of 45-minute treatments.

Due to the retrospective nature of the study, lack of well-controlled data collection, and overall complexity, the study was limited to simplified data collection of 3 main characteristics: symptoms of pain; symptoms of numbness; and condition of a wound, if present. These characteristics were noted for improvement, worsening, or staying the same, based on numerical scores or written records. Pain was measured with a visual analog scale of 0-10 at each visit, where 0 indicated no pain, 1 indicated very mild pain and so on, with 10 being the most intense pain, so numerical values were available. In this study, the actual pain numbers were recorded in the CRF and it was noted if the numbers had increased, decreased, or stayed the same for the course of a patient’s treatment. Numbness did not have a numerical score, so was evaluated from written notes as to severity and improvement of symptoms. This evaluation was physician-directed, based on patient interviews using the patients’ description of their pain, numbness, and activity levels, and on examinations. Wounds were measured by length, width, depth and assessment of tissue—granulation, slough, necrosis—and recorded so presence and change were easily monitored. Improvement was assessed by decrease in dimensions and increase in granulation, decrease in slough and necrosis, or closure. Once-weekly treatments with HVPC electrical stimulation continued, with some missed treatments due to patient illness or other conflicts, until symptoms had improved to the point at which the patient was satisfied. The minimum number of treatments performed in this study was 4, or 1 month of treatment. The longest number of treatments was 93, with a median of 19. The average number of treatments was 23 which, when done weekly, is less than 6 months. This was a retrospective look at actual treatments, treating to resolution and not based on a specific number of treatments, or specific number of weeks of treatment.

The type of neuropathy was diagnosed by the physician based on a complete and thorough history and physical examination, and in some cases nerve conduction testing to support or refute a diagnosis. It should be noted that all patients with diabetes in this study had type 2 diabetes.

In this study, wounds were not directly treated with the electrical stimulation in the usual way, which is to place an AC electrode pad directly on the wound. The electrical stimulation in this study was used to treat neuropathy as an adjunct to wound therapy. The carbon electrode pads were positioned on opposing muscle bundles, such as in the foot or calf, and treatment given to the muscle groups. Wounds did not have an electrode pad placed directly on them unless they happened to be at the site of the planned pad placement.

Medication use was documented in the charts, and it was noted whether each patient was using statins at the initial visit, and if so, if the statins were stopped.

All but 2 patients initially had objective evaluation of their neuropathy with nerve conduction testing (NCT) (NC-stat, Neurometrix, Tumwater, WA). Small fiber biopsies were not done routinely so evaluation of small fiber neuropathy was not available, which is more specific for neuropathy than NCT, which tests long fibers. Eleven patients had a second NCT to monitor progress.

**Keypoints**

- A total of 48 charts were accepted for review.
- Treatment modalities evaluated were treatment with high volt pulsed current (HVPC) electrical stimulation and stopping statin therapy.
- All 48 patients in this study were treated with HVPC electrical stimulation; 13 patients also stopped taking statins.
Results

Characteristics of the patient population are seen in Table 1. Participants in this study were predominantly white, and the majority were male. The age range was 47-89 years with an average age of 68 years. The number of treatments each patient received ranged from 4-93, with an average of 23 and a median of 19.

While diabetic neuropathy was the most common type treated, there were 5 other types of neuropathy identified among the study population (Table 2). Additionally, the patients with neuropathy were divided into 2 sets, diabetic and nondiabetic, with 25 (52%) cases of diabetic neuropathy, and 23 (48%) nondiabetic.

The number and percent of patients with each of the symptoms of pain or numbness and presence of a wound and the number and percent that improved, remained the same, or worsened over course of treatment (Table 3). Percent improvement in symptoms is significant, from 48% to 88%, with a total of 40 (83%) improved in at least 1 category. The time period used for measuring success varied according to patient outcome. The measurement period corresponds to the number of treatments, which in most of the cases in this study would also be the number of weeks. Time periods ranged from 4 weeks to more than 1 year. Of the 48 patients in this study, 42 (88%) had pain, 41 (85%) had numbness, and 26 (54%) had a wound. Overall, 83% of patients improved in at least 1 area—pain, numbness, or wound—with treatment. Observation of differences in symptom improvement between diabetic and nondiabetic neuropathy is summarized in Table 4. For patients with diabetic neuropathy, 54% improved in pain symptoms vs 40% of patients with nondiabetic neuropathy. For numbness, 54% of patients with diabetic neuropathy improved vs 63% of patients with nondiabetic neuropathy. Overall, 88% of wounds improved, 91% with nondiabetic neuropathy and 87% with diabetic neuropathy. The differences in these 2 groups, diabetic vs nondiabetic, were not statistically significant.

Excluding treatment outliers with greater than 50 treatments, there was a statistically significant correlation between number of treatments and improvement in symptoms, with $r = 0.3808$ and $P = 0.0099$. Of interest, of the 13 patients who were initially taking a statin and stopped, 100% improved in at least 1 symptom. Of the 6 patients who did not stop taking a statin, 83% showed improvement in at least 1 symptom. If the 13 who stopped taking statins were removed from the total group, the overall percent improved would be 77%, still a significant number.

For the 46 patients receiving initial NCT, 17 (42%) tested severe, 2 (5%) were moderate, 24 (60%) were mild, and 2 (5%) were negative. A negative NCT reading does not negate the diagnosis of neuropathy, but simply means the nerve deficits are not measurable with the system used. Eleven patients had a second NCT, resulting in 1 patient being reduced from severe to mild, 2 from mild to negative, and 1 from mild to severe; 6 patients' readings remained the same. Overall, 36% had improvement in objective NCT, suggesting reversal of neuropathy. The number of observations does not allow clinical significance to be determined using chi square; however, if the sample were larger, this distribution of initial and final results would be clinically significant. Results of NCT are shown in Table 5.

Discussion

While the characteristics chosen to study—pain, numbness, and the condition of a wound—are standard
and well-known problems with neuropathy, the treatment modalities studied may seem somewhat arbitrary, but have actually been chosen because of clinical efficacy and/or known published results. While there is no other published study using the specific HVPC electrical simulation system evaluated in this study for PN, the Oklahoma Veterans Center, Claremore, OK, performed a study to evaluate patients with diabetic PN receiving HVPC treatments for 45 minutes 3 times weekly for a range of 3 to 25 treatments. (Unpublished data, MicroVas, February 2006.) While the results for the 21 patients included in the study are not published, a 62% improvement in neuropathic symptoms and 78% improvement in wounds was reported. Treatment parameters were not specified. There have been a few published studies showing success of electrical stimulation treatment for neuropathy, or its effectiveness in generating healing and regeneration of tissues. The choice to stop statin medication in the current study was due both to clinical experience and published research. Published research from a Danish study indicates a 26-fold increase in risk of neuropathy with a statin medication.

The fact that 83% of patients improved in at least 1 symptom with treatment would suggest that neuropathy can be successfully treated. The primary treatment in this study was HVPC electrical stimulation used for each patient at each weekly session, with discontinuation of statins as a secondary treatment for 13 (27%) patients, of which 19 were eligible. There was a statistical correlation between number of treatments and improvement in symptoms. One of the more remarkable findings is 100% improvement in pain, numbness, and wound condition in patients who stopped their statin. Improvement was measured at the end of the study and patients were not followed after that. Because of the small sample, this is not a statistically significant finding, yet it is quite suggestive and certainly mirrors the findings in clinical practice at the study site. It is also of significant interest that 36% of patients had resolution or improvement of their neuropathy as measured by objective NCT; yet again, not a statistically significant finding due to small sample size.

**Key Points**

- Overall, 83% of patients improved in at least 1 area—pain, numbness, or wound—with treatment.
- Of the 13 patients who were initially taking a statin and stopped, 100% improved in at least 1 neuropathic symptom.
- Of the 6 patients who did not stop taking a statin, 83% showed improvement in at least 1 neuropathic symptom.

### Table 3. Symptoms and results with treatment.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Number</th>
<th>Percent (%)</th>
<th>Improved (#/%)</th>
<th>Same (#/%)</th>
<th>Worse (#/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>42</td>
<td>88</td>
<td>20/48</td>
<td>16/38</td>
<td>6/14</td>
</tr>
<tr>
<td>Numbness</td>
<td>41</td>
<td>85</td>
<td>24/58</td>
<td>16/39</td>
<td>2/5</td>
</tr>
<tr>
<td>Wound</td>
<td>26</td>
<td>54</td>
<td>23/88</td>
<td>1/4</td>
<td>2/8</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>100</td>
<td>40/83</td>
<td>7/15</td>
<td>1/2</td>
</tr>
</tbody>
</table>

### Table 4. Improvement in symptoms.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Diabetes Mellitus Neuropathy (%)</th>
<th>Nondiabetes Mellitus Neuropathy (%)</th>
<th>Overall (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>54</td>
<td>40</td>
<td>48</td>
</tr>
<tr>
<td>Numbness</td>
<td>54</td>
<td>63</td>
<td>58</td>
</tr>
<tr>
<td>Wound</td>
<td>87</td>
<td>91</td>
<td>88</td>
</tr>
</tbody>
</table>

### Table 5. Nerve conduction testing.

<table>
<thead>
<tr>
<th>Test</th>
<th>Total</th>
<th>Severe (#/%)</th>
<th>Moderate (#/%)</th>
<th>Mild (#/%)</th>
<th>Negative (#/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>46</td>
<td>17/42</td>
<td>2/5</td>
<td>24/60</td>
<td>2/5</td>
</tr>
</tbody>
</table>
Conclusion

Use of HVPC electrical stimulation and its strategic combination with stopping statins is associated with significant reduction, or complete reversal, of PN symptoms. In this study, more than 80% of people with neuropathy had reduction in symptoms of pain, numbness, or a wound, and 36% had reversal or improvement of their neuropathy by objective testing. Overall, 88% of wounds in this study were improved. The findings in this retrospective study are suggestive enough to warrant further prospective studies in the use of 1 or both of these noninvasive interventions to manage PN and to treat wounds associated with this condition.

Acknowledgment

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References


