Comparison between Different Modulated Electrical Current on Painful Foot in Diabetic Polyneuropathic Patients

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Abstract

Purpose of the Study: To evaluate the influence of three different modulated current on reducing foot pain diabetic neuropathy (DN) patients and to determine the most effective modulated current.

Subjects: Twenty-eight female patients with (eight to eleven years of diabetes mellitus) painful diabetic neuropathy and abnormal results of nerve conduction studies were randomly recruited in this study. Their age ranged from 48 to 60 years old. Patients were assigned randomly into four equal groups of seven.

Methods: Group 1 (G1) received low frequency modulated current (LFMC), group 2 (G2) received high frequency modulated current (HFMC), group 3 (G3) received low-high frequency modulated current (L-HFMC) and group 4 (G4) received sham procedure (control group) for a period of three weeks (12 sessions). The four groups were assessed pre and post treatment for pain intensity via Visual analogue scale (VAS) and nerve conduction studies (peroneal motor conduc-tion studies, sural sensory conduction studies).

Results: Pain was significantly decreased in group 1 (G1) who received (LFMC) more than both; group 2 (G2) that received (HFMC) & group 3 (G3) that received (L-HFMC), while pain in group 4 (G4) was not significantly decreased.

Conclusion: Low frequency modulated current is more effective in reduction of diabetic polyneuropathic pain when compared to other modulated current.

Key Words: Diabetic sensorymotor polyneuropathy – Modulated current – Nerve conduction studies – Numerical analogue scale – Painful foot.

Introduction

DIABETES is the leading cause of neuropathy in the Western world and neuropathy is the most common complication and greatest source of morbidity and mortality in diabetic patients [1]. Diabetic peripheral neuropathy is a consequence of diabetes-mediated impairment in blood flow to vasa nervosum and resultant hypoxia of Nerves [2]. Distal symmetrical sensorymotor polyneuropathy is the commonest form of diabetic sensorymotor poly-neuropathy (DSP) accounting for about 75% [3]. Small fiber involvement produces burning sensations. Involvement of large fibers tends to produce a tight band like feeling or an electrical tingling sensation [1]. Sensorimotor neuropathy is the primary risk factor for the development of diabetic foot ulcer, which is responsible for 85% of lower-extremity amputations in diabetes patients [4]. Pain developed sometimes during the course of diabetes, 34% of patients reported painful symptoms referable to their neuropathy. Most patients have localized pain at lower extremities, primarily the soles and toes, that interfere with sleep, quality of life and psychological status of patients painful symptoms vary from severe dysesthetic burning with nocturnal worsening (feet & ankle), cutaneous contact discomfort, thermal analgesia, and paresthesia [5,6]. Painful DSP is often resistant to treatment with simple analgesics, medications such as narcotic analgesics, tricyclic antidepressant, anti-convulsants, phenothiazines and nonsteroidal anti-inflammatory drugs have all been used with limited success in treating painful DSP. In addition, the adverse effects as drowsiness, lethargy and unsteadiness are frequent and limit the use of pharmacological intervention [7]. The unsatisfactory results of pharmacological treatment attract the attention to applicate another alternative effective non-invasive symptomatic treatment, hence comes the role of inferential current.

Interferential Current Interferential current therapy involves the placement of two electrodes on the skin at a painful area or the spinal nerve root associated with a painful region. Alternating currents of medium frequency are applied through the electrodes to the treated area. The currents rise and fall at different frequencies. It is theorized that the low frequency of the interferential current causes inhibition or habituation of the nervous
system, which results in muscle relaxation, suppression of pain and acceleration of healing [8]. Interferential current therapy (IFC): This type of stimulation is characterized by the crossing of two electrical medium, independent frequencies that work together to effectively stimulate large impulse fibers. These frequencies interfere with the transmission of pain messages at the spinal cord level. Because of the frequency, the Interferential wave meets low impedance when crossing the skin to enter the underlying tissue. This deep tissue penetration can be adjusted to stimulate parasympathetic nerve fibers for increased blood flow [9].

The purpose of the study was to evaluate the effects of three different modulated interferential current on pain relief in DSP patients and to determine the most effective modulated current in reducing foot pain in DSP patients.

**Material and Methods**

1- **Subjects:**

Twenty-eight diabetic female patients represented with painful feet and abnormal results of nerve conduction velocity were randomly participated in this study. Their age ranged from 48 to 60 years old. Patients were referred from Neurological clinic of medical insurance hospital and from Out-Clinic of Faculty of Physical Therapy, Cairo University. All patients were suffering from mild to moderate symptoms and having clinical and electrophysiological signs and symptoms of symmetric diabetic neuropathy of type I, II diabetes for a period ranged from six months to two years. Patients were excluded if they had unstable glycemic control or clinically significant systemic diseases other than diabetes mellitus that might have confounded interpretation of the study results, such as peripheral vascular disease, history of cancer, significant renal or hepatic disease, severe chronic pain (lasting all the day, not responding to medication), pregnancy, foot ulcers, superficial sensory loss of the foot. Group I (GI): received low frequency modulated current (LFMC), Group II (GII): received high frequency modulated current (HFMC), Group III (GIII): received low-high frequency modulated current (L-HFMC), Group IV (GIV): received Sham procedure (control group). Patients characteristics were represented in Tables (1,2).

2- **Instrumentation:**

1- **Assessment instruments:**

- Electroneurography Device (TOENNIS NEUROSCREEN PLUS DEVICE) was used to measure peroneal motor conduction velocity (PMCV) and sural sensory conduction velocity (SSCV). The device consisted of Screen, Bipolar stimulating electrode, Active recording, reference and ground electrodes and Computer system.
- Pin brick to assess pain sensation, cotton for fine touch.
- Tuning fork to assess vibration sense.
- Visual analogue scale for pain assessment (Fig. 1).

2- **Treatment Instrumentation:**

Phyaction 787 Series Device. Was used for the purpose of modulated electrical current. (The device had the ability to delivered modulated current).

3- **Procedures:**

a- **Assessment procedures (Clinical):**

1- Sensory assessment (pain, touch and vibration sense): Were done by two examiners while patient at supine lying position (each examiner had no any feedback about the other examiner results). Pain sensation was evaluated by pin-prick from toes all the way up until above the knee joint. Touch was evaluated by a piece of cotton passed from toes till above knee. Vibration sense was evaluated by a 128HZ tuning fork, applied on the lateral malleolus distally and on the patella proximally.

2- Pain level assessment: Level of pain was assessed by using 10cm numerical analogue scale (NAS, 0 = no pain; 10 = unbearable pain), which assesses the severity of pain in general [10]. Pain was assessed before and after the treatment program. Patients were informed about the nature of VAS and were asked to pick a number on the scale as an index for their pain level.

3- Electrophysiological evaluation: Were performed pre and post treatment (after 3 months). Patients' results were compared to the normal Egyptian population electrophysiological results. Evaluation included Sensory nerve conduction velocity (SNCV), latency and amplitude for sural nerve & Motor nerve conduction velocity (MNCV), latency and amplitude for peroneal nerve. Both lower limbs were evaluated (right, left). All patients were placed in comfortable supine lying position. Skin under the area of electrodes placement was cleaned by alcohol.

![Fig. (1): Numerical analogue scale](10).
Electrode placement for Common Peroneal Nerve (CPN):

Pickup: The active surface electrode was placed over Extensor Digitorum Brevis (EDB) muscle in the anterior lateral aspect of the proximal midtarsal area. Reference electrode: was placed 3cm distal to the pickup electrode. Ground electrode: was placed between the cathode of the stimulator and the active pickup electrode. Stimulating electrode: stimulation was applied slightly lateral to the midline in the lower third of the posterior aspect of the leg with the cathode distally about 17cm from the active electrode [13,14].

b- Treatment procedures:

Patients were randomly divided into four equal groups of seven. Group I (GI): received low frequency modulated current (LFMC), frequency (10HZ), duration (30min), Group II (GII): received high frequency modulated current (HFMC) frequency (100HZ), duration (30min), Group III (GI-III): received low-high frequency modulated current (L-HFMC) frequency (10-100HZ) duration (30min), the device was adjusted to raise and lower the frequency automatically during the period of stimulation, Group IV (GIV): received sham procedure (control group). Patients were relaxed in supine lying position, the modulated current were delivered bilaterally for both legs (the device was adapted to deliver two channels modulated current) with four electrodes, two electrodes for each leg.

<table>
<thead>
<tr>
<th>Electrode placement for CPN (CV, Latency, Amplitude)</th>
<th>GI (LFMC) Mean ± SD</th>
<th>GII (HFMC) Mean ± SD</th>
<th>GIII (L-HFMC) Mean ± SD</th>
<th>GIV (control) Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV. (MSEC)</td>
<td>Lt. 46.59±6.01</td>
<td>Lt. 45.6±5.02</td>
<td>Lt. 44.4±5.00</td>
<td>Lt. 44.8±5.03</td>
<td>0.65#</td>
</tr>
<tr>
<td>Lat. (MSEC)</td>
<td>Lt. 3.92±0.76</td>
<td>Lt. 4.14±0.82</td>
<td>Lt. 3.47±0.62</td>
<td>Lt. 3.89±0.51</td>
<td>0.52#</td>
</tr>
<tr>
<td>Amp. (MV)</td>
<td>Lt. 1.4±0.78</td>
<td>Lt. 1.52±0.99</td>
<td>Lt. 1.54±0.65</td>
<td>Lt. 1.51±0.43</td>
<td>0.7#</td>
</tr>
<tr>
<td>CV (M/SEC)</td>
<td>Lt. 28.30±2.2</td>
<td>Lt. 28.1±1.3</td>
<td>Lt. 27.35±2.1</td>
<td>Lt. 27.34±1.7</td>
<td>0.24#</td>
</tr>
<tr>
<td>Lat. (MSEC)</td>
<td>Lt. 13.45±1.2</td>
<td>Lt. 12.15±1.8</td>
<td>Lt. 14.42±2.2</td>
<td>Lt. 15.1±1.6</td>
<td>0.35#</td>
</tr>
<tr>
<td>Amp. (MV)</td>
<td>Lt. 3.7±0.54</td>
<td>Lt. 2.82±1.4</td>
<td>Lt. 2.72±5.2</td>
<td>Lt. 2.8±4.8</td>
<td>0.50#</td>
</tr>
</tbody>
</table>

Table (2): Demographic characteristics of patients.

<table>
<thead>
<tr>
<th>Patients characteristics</th>
<th>GI (LFMC) Mean ± SD</th>
<th>GII (HFMC) Mean ± SD</th>
<th>GIII (L-HFMC) Mean ± SD</th>
<th>GIV (control) Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54.2±4.12</td>
<td>55.2±3.11</td>
<td>55.2±5.17</td>
<td>57±5.51</td>
<td>0.4#</td>
</tr>
<tr>
<td>Duration of diabetes mellitus (years)</td>
<td>9.43±7.3</td>
<td>10.4±4.8</td>
<td>9.2±24</td>
<td>8.98±3.8</td>
<td>0.64#</td>
</tr>
<tr>
<td>Duration of Polyneuropathy (Months)</td>
<td>10.35±5.4</td>
<td>11.60±0.32</td>
<td>10.20±15</td>
<td>11.2±4.1</td>
<td>0.78#</td>
</tr>
<tr>
<td>Pain level assessment (VAS)</td>
<td>8.9±2.2</td>
<td>9.2±1.2</td>
<td>8.7±3.5</td>
<td>9.12±1.2</td>
<td>0.52#</td>
</tr>
</tbody>
</table>
Electrodes placement: Each electrode was socked with conductive gel for maximum conduction of current and one electrode was placed just below the head of fibula, the other electrode was placed over the dorsum of foot just lateral to the Tibialis anterior tendon.

Statistical analysis:

The arithmetic mean and standard deviation of the mean, One-way ANOVA test (to determine differences between the four groups pre and post treatment) and Tukey-Kramer multiple comparison test was used as post test if p-value less than 0.05 (To determine level of significant difference between the four groups) level of significance was chosen at p<0.05.

Results

The current study was designed to compare the effect of different modulated interferential current (with different frequencies) on foot pain relief in diabetic polyneuropathy patients. Twenty eight patients were participated in this study and randomly assigned into four equal groups of seven pain relief on both feet were measured before and after treatment using Numerical Analogue Scale (NAS) and electrophysiological changes nerve conduction studies) of both: peroneal & sural nerves were evaluated pre and post treatment for both feet. Results consisted of electrophysiological results (Peroneal nerve motor conduction velocity, motor distal latency, motor amplitude & Sural nerve sensory conduction velocity, sensory distal latency, sensory amplitude) and Clinical results.

A- Electrophysiological results:

Peroneal nerve results:

Peroneal Nerve Motor Conduction Velocity (MCV): There were non statistical significant differences between mean values of both Peroneal nerves (MCV) pretreatment among the four groups (p=0.2177): G1 was (47.07±3.6), G2 (46.55±4.26), G3 (46.53±3.1), G4 (46.50±3.7). While, post treatment there were highly statistical significant differences between all groups (p=0.0011): G1 (52.76±2.45), G2 (48.30±2.88), G3 (49.9±3.02), G4 (46.40±3.8) (Fig. 2).

Peroneal nerve distal motor latency (DML): There were non-statistical significant differences between mean values of both Peroneal nerves (DML) pretreatment among the four groups (p=0.9346): G1 was (4.2±0.07), G2 (4.19±0.45), G3 (4.15±0.82), G4 (4.13±0.77). While, post treatment there were statistical significant differences between all groups (p=0.05): G1 (3.42±0.48), G2 (3.90±0.76), G3 (3.75±0.57), G4 (4.13±0.58) (Fig. 3).

Peroneal nerve amplitude: There were non statistical significant differences between mean values of both Peroneal nerves amplitude pretreatment among the four groups (p=0.0918): G1 was (1.48±0.39), G2 (1.51±0.27), G3 (1.49±0.31), G4 (1.5±0.32) While, post treatment there were highly statistical significant differences between all groups (p=0.011): G1 (1.98±0.29), G2 (1.60±0.35), G3 (1.68±0.31), G4 (1.5±0.30) (Fig. 4).

Fig. (2): Pre & post treatment peroneal nerve motor conduction velocity means values of all groups.

Fig. (3): Pre & post treatment peroneal motor distal latency Means values of all groups.
Tukey-Kramer multiple comparison test was applied as posttest (*p*-values were less than 0.05) to determine level of significant difference between the four groups (Table 3). The results showed that G1 (received LFMC) was improved significantly more than all other groups (G2, G3, G4), while G3 results (received L-HFMC) were improved than G2 (received HFMC) & G4, but the improvement was not significant.

Sural nerve results: (Table 5).

Regarding sural nerve results for both lower limbs, there was a highly significant difference (**p**=0.000) between pre and post treatment results. Pre treatment Sural nerve responses were absent in 85% of all groups, while post treatment it was present for 100% of patients in G1, G2, G3. While it still absent in G4. (As there were 85% of patients with absent values, so statistical ANOVA test was not valid to be used, so percentage of changes was used to calculate the amount of improvement). In addition, pre treatment sural nerve results were present in 15% of all groups but with abnormal values (reduced SCV, Amplitude and prolonged latency) (Table 4). Regarding the post treatment results of G1, G2, G3, all the patients (100%) showed an improvement of sural nerve results (SCV, SDL, S Amplitude), but not reach to normal values, except 70% of G1 SCV, the patient reach to normal value, while 30% improved but not reach to normal. Also 60% of G1SDL reached to normal values and 40% were improved.

![Peroneal nerve amplitude means values of all groups.](image)

Fig. (4): Pre & post treatment peroneal nerve amplitude means values of all groups.

### Table (3): Comparison between peroneal nerve electrophysiological results for all groups treatment.

<table>
<thead>
<tr>
<th>Group 1 (G1)</th>
<th>Group 2 (G2)</th>
<th>Group 3 (G3)</th>
<th>Group 4 (G4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMCV Mean Difference</td>
<td>pm</td>
<td>PMDL Mean Difference</td>
<td>pm</td>
</tr>
<tr>
<td>G1XG2</td>
<td>4.46</td>
<td>0.001*</td>
<td>0.53</td>
</tr>
<tr>
<td>G1XG3</td>
<td>2.86</td>
<td>0.03*</td>
<td>0.33</td>
</tr>
<tr>
<td>G1XG4</td>
<td>6.36</td>
<td>0.000**</td>
<td>0.71</td>
</tr>
<tr>
<td>G2XG3</td>
<td>1.6</td>
<td>0.07#</td>
<td>0.2</td>
</tr>
<tr>
<td>G2XG4</td>
<td>1.9</td>
<td>0.05*</td>
<td>0.18</td>
</tr>
<tr>
<td>G3XG4</td>
<td>3.5</td>
<td>0.02*</td>
<td>0.38</td>
</tr>
</tbody>
</table>

**GI**: Group 1.  
**GII**: Group 3.  
**GIII**: Group 2.  
**GIV**: Group 4.  

PMCV: Peroneal Motor conduction.  
PMDL: Peroneal Motor distal latency.  
P Amplitude: Peroneal amplitude.

### Table (4): Percentages of changes of Sural nerve electrophysiological responses pre and post treatment for G1, G2 and G3.

<table>
<thead>
<tr>
<th>Response</th>
<th>Pre treatment</th>
<th>Post treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>85%</td>
<td>0%</td>
</tr>
<tr>
<td>Present</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td>Chi square</td>
<td>20.000</td>
<td></td>
</tr>
<tr>
<td>p-value</td>
<td>0.000**</td>
<td></td>
</tr>
</tbody>
</table>

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Table (5): Percentages of Sural nerve changes (SCV, SDL, Amplitude) pre and post treatment for all groups.

<table>
<thead>
<tr>
<th>Percentages of present responses</th>
<th>Pre treatment</th>
<th>Post treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G1 G2 G3 G4</td>
<td>Normal Improved not reaching normal</td>
</tr>
<tr>
<td>Conduction velocity</td>
<td>100% (Reduced) 70% 0% 0% 0% 30% 100% 100% 0%</td>
<td></td>
</tr>
<tr>
<td>Distal Latency</td>
<td>100% (Prolonged) 60% 0% 0% 0% 40% 100% 100% 0%</td>
<td></td>
</tr>
<tr>
<td>Amplitude</td>
<td>100% (Reduced) 0% 0% 0% 0% 100% 100% 100% 0%</td>
<td></td>
</tr>
</tbody>
</table>

B- Clinical results:

*Results of numerical analogue scale (assessment of pain):*

There were non-statistical significant differences between pretreatment mean values of pain score among the four groups (\(p=0.083\)). While, post treatment there were highly statistical significant differences between all groups (\(p=0.011\)) (Table 6, Fig. 4). The results also showed that, pain was reduced significantly in G1 (received LFMC) when compared to other groups (G2, G3, G4) (\(p=0.001\)). Pain also significantly reduced in G3 (received L-HFMC) when compared to G2 (received HFMC) (Fig. 5, Table 6).

Table (6): Comparison between pain score values post treatment for all groups.

<table>
<thead>
<tr>
<th></th>
<th>Mean difference</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1XG2</td>
<td>3.71</td>
<td>0.003*</td>
</tr>
<tr>
<td>G1XG3</td>
<td>2.4</td>
<td>0.02*</td>
</tr>
<tr>
<td>G1XG4</td>
<td>6.61</td>
<td>0.000*</td>
</tr>
<tr>
<td>G2XG3</td>
<td>1.31</td>
<td>0.093#</td>
</tr>
<tr>
<td>G2XG4</td>
<td>2.9</td>
<td>0.05*</td>
</tr>
<tr>
<td>G3XG4</td>
<td>4.21</td>
<td>0.007*</td>
</tr>
</tbody>
</table>

NAS: Numerical analogue scale.

*Significant.

# Non significant.

**Discussion**

This study was designed to determine the most effective frequency interferential current in relieving polyneuropathy pain. The results showed that there was statistical significant relieving of foot pain after using different modulated interferential current, this was seen for G1 (LFMC), G2 (HFMC), G3 (L-HMFC). While G4 (sham procedure) showed non-significant changes. However, G1 (LFMC) showed significant improvement of electrophysiological examination & relieving of foot pain compared to other groups. The improvement of electrophysiological examination (peroneal motor conduction velocity, motor distal latency, amplitude & sural sensory conduction velocity, distal latency, amplitude) at group 1 that received low frequency modulated current of interferential could be explained as follows: The increase in conduction velocity mediated by an increase in endoneurial blood flow after electrical stimulation of peripheral nerves and increased nerve conduction velocity after an improvement in blood flow in the lower limbs, achieved through either revascularization or alternatively, due to action on neuron sodium channels [15]. Other evidence suggests that sodium channel expression in primary sensory neurons is altered in diabetic neuropathy [16], indicating a possible molecular basis for neuropathic pain. Confirmed that electrical stimulation induces cellular responses that involve the redistribution of integral membrane proteins, including calcium
channels [17] & increase in the number of myelin fibers and altered end neural vessels. Thus, the detected improvements in PMCV post treatment simply reflect some functional changes of the nerve. The results also revealed that the pain was significantly reduced in the first three groups; however, pain was significantly reduced in G1 more than G2 & G3. Group 1 received low frequency modulated interferential current, it was confirmed that Premodulated IFC appears to be more comfortable, more effective and be better accepted and tolerated by the patient [18]. It is believed that low frequency current excites nervous tissue to initiate endogenous analgesic mechanisms [19], its effect was more prolonged than that of G2, G3, this may be because low frequency modulated current is a medium frequency current in nature that exerts lower resistance to skin than high frequency. Therefore, low frequency interferential current (LFIC) is likely to be more effective in penetrating through the skin and stimulating the deep nerve tissues underneath [20]. Other studies confirmed that LFIC is an effective method for producing pain relief for up to 1 week and for up to 6 months when used with a twice-daily exercise program [21]. It is theorized that the low frequency of the interferential current causes inhibition or habituation of the nervous system, which results in muscle relaxation, suppression of pain and acceleration of healing [22,23]. However, G2 (received HFMC) & G3 (received L-HMFC) showed significant pain relief but less than G1, this could be due to the fact that high frequency current causes physiological blocking of pain transmission (blocking of c fibers). Probably involving the gate control theory, the physiological block and the endogenous pain inhibitory system. In addition, this may be due to the fact that LFC is a medium frequency current that exerts lower resistance to skin than HFC. Therefore, LFC is likely to be more effective in penetrating through the skin and stimulating the deep nerve tissues underneath. Other authors examined the effects of different IFC and TENS frequencies on sensory, motor and pain thresholds, they found that both IFC and TENS displayed a significant frequency dependent, but with more significant effect at interferential group [24]. IFC also elevates pain threshold when compared with no treatment and with sham group. Also application of IF current preventing the side effects of pain relieving drugs in diabetic polyneuropathy patient [25]. Nevertheless, premodulated IFC, delivered via two large electrodes, may be clinically more effective than the traditional true IFC arrangement in terms of depth efficiency, torque production, and patient comfort [26].

Conclusion: Interferential low frequency modulated current is a safe and effective therapy for neuropathic pain in diabetic patients with peripheral neuropathy and that it is able to modify some of the parameters of peripheral nerve function.

References


