PILOT STUDY OF THE EFFICACY OF PULSE STIMULATION TREATMENT (P STIM™) FOR CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY: A RETROSPECTIVE CHART REVIEW

Wesley Baas BS, Mary Ann Barnes MD, John Sacco MD, Christina Luberto MA, Sian Cotton PhD

Center for Integrative Health and Wellness, University of Cincinnati College of Medicine
Cincinnati, Ohio

Background
- Peripheral neuropathy is a common limitation to chemotherapeutic drugs
- Mechanism behind this neurotoxicity poorly understood, and no drug currently available that can prevent or cure this adverse effect
- Pharmacological treatments are typically first approach to pain management but can carry adverse side effects and have had limited efficacy
- Recent attention has focused on complementary and integrative medicine (CIM) as supplementary treatments for chemotherapy-induced peripheral neuropathy (CIPN)

- PSTIM is a clinically promising, yet understudied integrative modality used in treatment of pain.
- Limited research is available about the utility of PSTIM in treatment of CIPN

Present Study

Purpose: To examine the potential benefits of PSTIM in the treatment of chemotherapy-induced peripheral neuropathy

Hypothesis: PSTIM therapy will be associated with reduced pain and increased functioning for patients with CIPN

Methods

Design: Mixed-method retrospective chart review
Participants: Patients receiving PSTIM therapy for CIPN

Quantitative Measures
- Pain: Numerical Rating Scale (NRS) ranging from 1 (no pain) to 10 (greatest pain)

Qualitative Data
- Patient interview responses on subjects such as pain, functional improvement, quality of life, and functional outcomes (e.g. gait/balance) were assessed

Procedure
- Charts identified of patients receiving PSTIM therapy for CIPN by an integrative oncologist (JS) between 1/2012-11/2013 (N = 98).
- Charts reviewed for a) demographic/clinical variables (e.g., number of PSTIM treatments); b) patient pain ratings pre-post PSTIM; and c) functional outcomes

Data Analysis
- 18 patients had pre-post pain scores available for quantitative analysis
- Paired samples t-tests used to compare pain scores pre- and post- treatment
- Qualitative content analysis conducted on additional 40 charts, 8 of which were drop-outs (i.e., PSTIM device placed but no follow-up).

Paired Samples T-test

<table>
<thead>
<tr>
<th></th>
<th>M (diff)</th>
<th>SD</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-PSTIM Pain Rating</td>
<td>4.94</td>
<td>1.55</td>
<td>13.52</td>
<td>17</td>
<td>.000</td>
</tr>
<tr>
<td>Post-PSTIM Pain Rating</td>
<td>3.17</td>
<td>1.34</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. M = mean; SD = standard deviation; t = paired-samples t score; df = degrees of freedom; p = p-value, alpha set at .05

Results

- Neither age nor number of treatments were associated with improvement in pain
- 59% of patients with qualitative data (n=19) reported significant improvements in pain and 25% (n=8) reported mild improvements in pain following PSTIM
- Functional improvements, including improved gait, balance, and activities of daily living were reported often

Conclusion and Future Directions

- PSTIM was associated with significant improvements in pain, and significant functional improvements in patients with CIPN
- Study limited by retrospective nature. Quantitative and qualitative data inconsistently collected across all patients
- Nevertheless, preliminary results suggest PSTIM™ may be useful non-pharmacologic treatment for patients with CIPN
- Further controlled studies using prospective research designs and active control groups is warranted

Funding: UC Center for Integrative Health and Wellness

What is P-STIM?

P-STIM™ is a patented, FDA approved peripheral nerve stimulator. It is a battery powered device that provides intermittent, low frequency impulses to specific peripheral nerves located in the ear.