The effect of high tone external muscle stimulation on polyneuropathy: a systematic review and meta-analysis

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Authors’ Contribution: A – Study design; B – Data collection; C – Statistical analysis; D – Manuscript Preparation; E – Funds Collection

DOI: https://doi.org/10.58962/HSR.2024.10.2.83-94

How to Cite

Abstract

Background and purpose. High-tone therapy, also known as High-Frequency External Muscle Stimulation (HTEMS), is a more recent and unique form of electrotherapy treatment. Unlike traditional electrotherapy methods, which use a single frequency, high-tone therapy modulates both frequency and amplitude to deliver more energy to the tissues. The options for treating neuropathy associated with any illness, including diabetes, are limited, especially non-pharmacological therapies. This review aims to investigate the evidence of the effectiveness of high-tone external muscle stimulation (HTEMS) for patients with polyneuropathy.

Materials and Methods. Google Scholar, Scopus, web of Science, PubMed, EMBASE, the Cochrane Central Register of Control Trials (CENTRAL), and Physiotherapy Evidence Database (Pedro) databases from inception to February 2022. We restricted the search to articles published in English only. Randomized controlled trials (RCTs) of HTEMS for peripheral neuropathy were included. Two independent reviewers screened the articles for eligibility, extracted the data, and assessed the risk of bias in eligible studies. Meta-analysis was performed using the random-effects model. The remaining results were presented using descriptive methods. The risk of bias was assessed using the PEDro scale.

Results. Six articles fulfilled the eligibility criteria with 487 participants. Most trials have focused on investigating the effectiveness of HTEMS in treating diabetic polyneuropathy and entrapment neuropathies. Overall, HTEMS provided a slight, but not clinically significant, reduction in pain and Katz index scores compared with mean control difference MD: 5.16; 95% CI, -15.6 to 4.73; p>0.05 and MD: 1.06; 95% CI, -0.22 to 2.33, p>0.05 respectively.

Conclusions. HTEMS has been proven to be more efficient in most aspects, such as reduction in pain intensity and Katz index scores in patients with polyneuropathy compared to other treatment options. The included trials presented methodological issues and high heterogeneity, preventing the establishment of any firm recommendations to support or refute the use of HTEMS as a strategy for managing neuropathic pain.

Keywords: electrical stimulation, high tone power therapy, peripheral neuropathy, neuropathic pain, neuro-modulation
Передумови та мета дослідження. Терапія високим тоном, також відома як високочастотна зовнішня стимуляція м'язів (HTEMS), є новою та уникальною формою електротерапії. На відміну від традиційних методів електротерапії, які використовують одну частоту, високотональна терапія модулює як частоту, так і амплітуду, щоб доставити більше енергії до тканин. Варіанти лікування невропатії, пов’язаної з будь-якою хворобою, включаючи діабет, обмежені, особливо нефармакологічна терапія. Цей огляд має на меті дослідити докази ефективності зовнішньої м’язової стимуляції високого тонусу (HTEMS) для пацієнтів із полінейропатією.

Матеріали та методи. Бази даних Google Scholar, Scopus, web of Science, PubMed, EMBASE, Кокранівського центрального реєстру контрольних досліджень (CENTRAL) і Physiotherapy Evidence Database (Pedro). Ми обмежили пошук статтями, опублікованими лише англійською мовою. Були включені рандомізовані контролювані дослідження (РКД) HTEMS для периферичної нейропатії. Два незалежні рецензенти перевірили статті на придатність, витягли дані та оцінили ризик упередженості в придатних дослідженнях. Мета-аналіз проводився з використанням моделі випадкових ефектів. Решта результатів представлено за допомогою описових методів.

Результати. Шість статей відповідали критеріям прийнятності з 487 учасниками. Більшість досліджень було зосереджено на дослідженні ефективності HTEMS у лікуванні діабетичної полінейропатії та нейропатії з високим тонусом. Загалом HTEMS забезпечував невелике зниження болю та індексу Катца порівняно із середньою контрольною різницею MD: 5,16; 95% ДI, від -15,6 до 4,73; p>0,05 і MD: 1,06; 95% ДI, від -0,22 до 2,33, p>0,05 відповідно.

Висновки. Доведено, що HTEMS є більш ефективним у більшості аспектів, таких як зменшення інтенсивності болю та індексу Катца у пацієнтів з полінейропатією порівняно з іншими варіантами лікування. Включення випробування представляли методологічні проблеми та високу неоднорідність, що переоцінивало створення будь-яких твердих рекомендацій на підтримку або спростування використання HTEMS як стратегії для лікування невропатичного болю.

Ключові слова: електротімус, високотональна енергетична терапія, периферічна нейропатія, нейропатичний біль, нейромодуляція.
Introduction

High-tone therapy or High-frequency external muscle stimulation (HTEMS) is a newer and different type of electrotherapy treatment procedure that, in comparison to the conventional electrotherapy methods, uses a specific frequency in high-tone therapy frequency and amplitude that are concurrently modulated; this allows delivery of more increased energy towards the tissues. In recent years, significant attention has been directed toward applying high-tone therapy in treating various disorders [1]. High-tone therapy, or HTEMS, is a new alternative to electrotherapy methods for managing neuropathy. Several hypotheses have been developed but have not been confirmed to explain the efficiency of high-tone therapy [2]. The mechanism of High-tone therapy action may be attributed to normalizing tissue metabolism. Compared to the conventional electrical stimulation treatment that stimulates muscles and nerves, researchers have suggested that tissue metabolism may be impacted using high-frequency external muscle stimulation through cell membrane fluctuation combined with the increment of cell energy potential [3]. Applying a wide array of frequencies makes it possible to oscillate the tissue structures and metabolism; similarly, cell processes can be normalized.

The function of Peripheral neuropathy affects the Aβ (where touch and vibration are mediated by myelinated fibers), C-fiber (where hot temperature perception and thermal discomfort are mediated by unmyelinated fibers), and Aδ (where thinly myelinated fibers involved in cold perception and thermal pain). Peripheral nerves have less or more severe damage leading to P.N. (sensory, motor, and autonomic nerves). A single nerve, multiple nerves in various regions, or many nerves may all be impacted by P.N. [4]. Weakness, numbness, and discomfort are commonly present along with peripheral nerves. Patients frequently describe the pain in their hands and feet as stabbing or tingling [5]. Excessive sensitivity to touch, discomfort while performing daily activities, falling and losing balance and coordination [6], muscle weakness, and paralysis if the motor units are affected [7]. In peripheral neuropathy, pain is a common symptom that significantly lowers patients' quality of life. Peripheral vascular disease and peripheral poly-neuropathy caused an average of 10% and 13% of pain causes, respectively [5]. Nonpharmacologic approaches are becoming more significant to display fewer side effects. Meditation, hypnosis, and other relaxation methods sadly have little practical use. Aerobic exercise has proven its efficacy in altering the beginning or possibly stopping the progression of diabetic PPN. Even though physical activity is highly advised for patients with PPN, most patients have poor compliance due to associated co-morbidities and low functional capacity. Numerous electro-medical therapies play a vital role in pain treatment [6].

The options for treating neuropathy associated with any illness, including diabetes, are limited, especially non-pharmacological treatments. The limitations may be why approximately 50% of patients undergoing peripheral neuropathy fail to report or seek medical help [8]. In many cases, medical personnel prescribes treatments such as anticonvulsants, analgesics, or antidepressants; the responses to these treatments vary significantly depending on the patients and the severity of their neuropathy. Numerous studies show that non-pharmacological therapies, including high-tone external muscle stimulation, promote a better quality of life for patients experiencing peripheral neuropathy than pharmacological options. Findings of multiple randomized trials examining the different types of electrical stimuli report positive outcomes, including improved sensitivity and reduced pain due to HTEMS in peripheral neuropathy patients [9].

Previous comprehensive reviews and meta-analyses of randomized studies found that electrical stimulation of the muscles was superior to placebo. However, the studies either reported conflicting results or had small sample sizes for the placebo groups, reducing the studies' reliability. A detailed systematic review of the data collected from the studies would allow for a more concise and precise analysis of electrical muscle stimulation's efficacy, safety, and benefits. Furthermore, the outcomes would be significant in the possible dissemination of electrical muscle stimulation for neuropathy treatment. Therefore, this study aims to systematically review the efficacy of neuropathy treatment using HTEMS in pain intensity and rate of recovery in polyneuropathy patients compared with a placebo or another intervention.
Materials and Methods

Literature Search

After department approval, the systematic review protocol was registered on PROSPERO (CRD42022314709). The study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. [10].

Until February 2022, Google Scholar, Scopus, WoS, PubMed/EMBASE, the CENTRAL, and the Physiotherapy Evidence Database were combed through. The studies were selected according to their relevance to the research topic. All sources were authored in the English language. The study designs exclusively included randomized controlled trials; therefore, all reviews and cohort studies that were not randomized were excluded. In addition, the search was limited to scholarly works and peer-reviewed articles published under conventional channels; any unpublished randomized controlled trials were excluded. Therefore, all articles written in any language other than English authored before 1999 or irrelevant to the research topic of HTEMS for neuropathy were excluded. The keywords used in the online database research included "high-frequency external muscle stimulation" OR "high tone power therapy" OR "high tone external muscle stimulation" AND "peripheral neuropathy" OR "Uremic peripheral neuropathy" OR "diabetic polyneuropathy."

Guidelines and Selection Criteria

After the initial selection of the randomized controlled trials, their abstracts and titles were skimmed to examine their significance to the research topic. They were also scrutinized to evaluate whether or not they met the predefined eligibility criteria. Articles that fulfilled the predefined eligibility criteria for the systematic review were fully read independently by Dr. Mariam Omran to determine their implication and relevance for the research. All differences were handled through consensus or consultation with Prof. Dr. Fatma Seddik.

Data Extraction

The authors name, year of publication, sample size, intervention characteristics such as frequency, duration, and intensity, patients' baseline data such as mean age, the proportion of females, the condition being studied, average pain before randomization, medications and duration of symptoms, and trial duration were all recorded in the articles. The treatment options included HTEMS, placebo or sham treatment, drug treatment, or other physical therapy interventions. The Cochrane Revman Software was used to conduct a meta-analysis of the different sub-group data collected from the randomized controlled trials; a descriptive analysis of the collected data was also completed. The PEDRO-P scale is an 11-item rating scale that assesses the included studies' internal and statistical validity. Scoring of the PEDRO-P scale is a well-disciplined and systematic process in which all items are graded based on specific criteria except item 1, which does not enter the final score. External validity is determined by grading the 1st item, while internal validity is determined based on scores of items 2-9. Finally, statistical validity is determined based on the grades of items 10 and 11. During the data extraction procedure, discrepancies about any element of the chosen articles were handled by consensus or consultation with Prof. Dr. Fatma Seddik.

Results

Study Selection

Using the keywords mentioned above, 1878 studies were found in the first search of the online databases. After duplicates were deleted, 714 studies remained. To determine their significance for the systematic review, the abstracts and titles of the 714 studies were scanned to determine their suitability after thorough screening; only 123 articles remained. The six articles that met the predetermined eligibility requirements were identified. Figure 1 depicts the PRISMA diagram for the selection method.
Fig. 1. Study selection and screening

Table 1

<table>
<thead>
<tr>
<th>Author</th>
<th>Intervention Characteristics</th>
<th>Study Design</th>
<th>Patient Characteristics</th>
<th>Sample size</th>
<th>Trial Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Alshimy et al., 2020)</td>
<td>HTT Group: 4,096 Hz – 32, 768Hz Control Group: CTG</td>
<td>RCT</td>
<td>46-56 years old. All T2DM patients with a history of 10 years were evaluated using the Neuropathy Disability Score (NDS).</td>
<td>HTT (n = 20) or CTG (n = 20)</td>
<td>Four weeks</td>
</tr>
</tbody>
</table>
(El-Regal et al., 2021) High Tone Power Therapy Control: traditional physical therapy program (AROM exercises for L.L., gentle manual stretching practices for L.L., and graduated gait training). RCT Ages ranged from 50-60 years old. Group-1: (n=30) Group-2: (n=30) 12 weeks

External muscle stimulation: 4,096 Hz to 32,768 Hz Control: TENS RCT 18-80 years old HbA1c values were <11% TENS (n=21) HF (n=20). Three days

(Kempf et al., 2018) HTEMS: 4,096 Hz to 32,768 Hz Control: 100Hz electrodes. RCT H1T2: 57±14 years) T1H2: 57±13 years) Patients had persistent sciatica that had been present for at least three months H1T2: 59 T1H2: 41 Five days

(Shady et al., 2021) Study group: HiTOP Control group: TENS RCT Study group: 37.0 ± 5.07 years Control group: 37.93 ± 3.86 years Study group: (n=15) Control group: (n=15) Four weeks

(Petersen et al., 2021) Study group: High-frequency (10-kHz) Spinal Cord Stimulation + CMM Control: CMM alone RCT 60.8 ± 10.7 216 patients 5 to 7 days

### Study Characteristics

Six RCTs [1,11–15] The meta-analysis included 457 patients who received high-frequency external muscle stimulation or were in the control group. 40 to 216 patients were included in each sample. The time between follow-ups was anywhere from three days to twelve weeks. Three studies were conducted in Egypt [12,14-15], two studies in Germany [3,13], and one study in the United States [11] (Table 1).

### Assessment of Quality

According to the PEDro scale Tool, included studies have a low risk of bias overall. Eligibility criteria were identified in 6 studies. Random sequence generation was used in 6 studies. However, the concealed allocation wasn’t determined in 4 studies. Aim to treat analysis, between-group analysis, point estimates, and variability were all placed in the six included studies (Table 2).

### Profiles of the patients

Profiles of the patients showed related parameters across the selected studies (Table 1). Most subjects were in their 18 years- 80 years. Females (n=229) represented 50.1% of trial participants. The subjects' diagnoses were: Diabetic neuropathy [11,12,15], Carpal tunnel syndrome [14], and Chronic sciatica [13].

### Outcome indicators

**VAS**

Three trials with a total of 346 patients reported on VAS scores. [13] used a 100-mm VAS score to assess patients' pain with chronic sciatica. Average pain over five days was measured before and after the end of the treatment program. A significant interaction was found (pretest= 56±21; posttest= 45±21, p=<0.001) in the HTEMS group, and no significant interaction was found in the control group (pretest= 59±19; posttest= 56±19, p>0.05). [14] Used a 100-mm VAS score to assess pain intensity in patients with carpal tunnel syndrome (CTS). There was a significant difference between the HTEMS group (posttest= 1.33±0.48) and Control group (7.06±1.33) with p-value = 0.001*. [11] found a significant difference between high frequency (10-kHz) spinal cord stimulation and conventional medical treatment p <0.001 at three months follow-up in VAS scores.
Changes to Boston Carpal Tunnel Questionnaire (BCTQ)

One study reported a difference in BCTQ scores with 30 patients. HTEMS has a significant improvement in mean changes of the BCTQ scores (CTQ-SSS= 1.4±0.63, CTQ—FS= 1.46±0.74) at four weeks follow up compared to the BCTQ score (CTQ-SSS= 2.8±1.01, CTQ—F.S. =3.13±0.91) p<0.001).

Changes in electrophysiological parameters

One study reported changes in electrophysiological parameters [15]. There was a significant difference between the Median nerve sensory peak latency of the HTEMS group (2.71±0.75) compared to the control group (3.88 ±0.89) with p-value= 0.0001, Median sensory nerve amplitude of the HTEMS group (19.43±5.91) compared to the control group (12.67±4.15) with p-value= 0.0001, Median sensory nerve conduction velocity of HTEMS group (45.72±7) compared to the control group (39.8±6.67) with p-value= 0.009, sural sensory nerve peak latency of HTEMS group (4±0.46) compared to the control group (5.49±0.85) with p-value= 0.0001, sural sensory nerve amplitude of HTEMS group (6.02±1) compared to the control group (4.63±0.76) with p-value= 0.0001, the sural sensory nerve conduction velocity of HTEMS group (38.71±2.13) compared to the control group (32.73±2.71) with p-value= 0.001.

Changes in the patient's degree of symptoms and pain

[3] used a subjective assessment via reporting the Complaints and pain severity on a scale ranging from one to ten to compare HTEMS to TENS in patients with symptomatic diabetic polyneuropathy. For treating the signs of non-painful neuropathy, HTEMS was more successful than TENS. (HTEMS: 100%, TENS: 44%, p<0.05) and painful neuropathy (HTEMS: 69%, TENS: 25%, p<0.05). The responders were comparable regarding the mean symptom intensity's decrease during the experiment.

Changes in the KATZ index

Two studies reported change in 5 with a total of 100 patients. [12] found no significant interaction of KATZ index score between HTEMS (4.13±0.5) and control (3.73±0.86) with p value= 0.587. While [15] found a significant interaction between HTEMS (5.4±0.59) and control (3.7±0.47) with p value= 0.001.

Changes of HbA1c%

One study reported a change in HbA1c% score with 60 patients. [12] found a significant interaction of HbA1c% score between HTEMS (6.35±0.36) and control (6.14±0.38) with p value= 0.036.

Side effects

One study reported side effects (such as infection, wound dehiscence, impaired healing, Deceive extrusion, etc.) with 216 patients. 18 patients reported adverse events in the HTEMS group, with two reporting severe adverse events. In contrast, no patients reported adverse events in the conventional medical treatment group.

Meta-Analysis

Regarding pain intensity, two studies were analyzed. The minimum number of included participants was 20, and the maximum number of included participants was 59. The overall number of participants in the study group was 79, while the control group included 62. Peripheral neuropathy affected the study participants. Meta-analysis was conducted using a random-effects model. For the 0–10 Visual Analogue Scale (VAS), the primary outcome for HTEMS versus controls differed by -5.16 (95 percent confidence interval, -15.6 to 4.73), favoring the use of HTEMS. The difference that existed comparing both cases proved insignificant, with a P=0.01 value that was lower than the P-value (P=0.31). The chosen articles had low heterogeneity (P<0.001) and I^2 statistic = 83% (Figure 2).

Regarding the KATZ index, two studies were analyzed. The minimum number of included participants was 20, and the maximum number of included participants was 30. The overall number of participants in the study cohort was 50, with 50 in the control group. Peripheral neuropathy affected the study participants. Meta-analysis was conducted
using a random-effects model. For the KATZ Index, the secondary outcome for HTEMS versus controls differed by 1.06 (95 percent confidence interval, -0.22 to 2.33), favoring the use of HTEMS. The difference comparing both cases was considered statistically non-significant, with $P=0.01$ being less than the $P$-value ($P=0.10$). The chosen articles had low heterogeneity ($P<0.001$) and $I^2$ statistic = 96% (Fig. 2).

Fig. 2: HTEMS vs. TENS, outcome: for peripheral neuropathy symptoms and KatzIndex of Independence

### Risk of Bias

#### Pedro Scale

<table>
<thead>
<tr>
<th>Pedro Criterion</th>
<th>Alshimy et al., 2020</th>
<th>El-Regal et al., 2021</th>
<th>Reichstein et al., 2005</th>
<th>Kempf et al., 2018</th>
<th>Shady et al., 2021</th>
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### Sackett Scale

To establish the amount of evidence, the Sackett scale was employed. Based on the selected studies, the level of evidence associated with this study is level 1A. This result was obtained because three high-quality randomized controlled trials on the PEDRO scale have a rating of more than 6. This equals solid evidence.

### Discussion

The present study showed that treatment with HTEMS enhances neurophysiologic measures which focus on the change of pathogenesis of neuropathy patients. All the six RCTs included in the analysis showed that high-frequency external is quite effective for treating peripheral neuropathy, including diabetic neuropathy, tarsal tunnel syndrome, median neuropathy, radial neuropathy, or Para-neoplastic polyneuropathy, among others. According to the current analysis, integrating high-tone power therapy is a statistically significant improvement in patients' quality of life and general functioning. Similar findings have been realized in previous studies. The promising results of the present studies associated with high-tone therapy can modify peripheral neuropathy progression without any other health implications [3]. However, the fundamental mechanisms of the working of high-frequency external have yet to be entirely understood. The possible justification for the high tone power therapy for peripheral neuropathy may be that electrical stimulations reduced the muscle cell excitability, neural adhesion molecule expression, and integrity of neuromuscular junctions and muscle fiber cross-sectional area in an animal model [16,17].

Chemotherapy-induced polyneuropathy is somewhat different for treatment using high-frequency external muscle stimulation. To date, limited research on the therapy in chemotherapy-induced polyneuropathy treatment has been carried out, even though the procedure is widely applied in clinical practice. A structured management regime with high-frequency external muscle stimulation can significantly improve the quality of patient care and
Symptom management of chemotherapy-induced polyneuropathy. Based on previous research, the medical implications of high-frequency external muscle stimulation on symptoms of chemotherapy-induced polyneuropathy may be pretty promising. Even though chemotherapy-induced polyneuropathy affects millions of patients with cancer globally, there is still limited evidence for treatment of the problem. Patients may respond differently to treatment using high-tone power therapy, depending on the chemotherapy administered.

Different mechanisms could explain the results of the RCTs in the current systematic review and meta-analysis. It is theoretically postulated that high-frequency external muscle stimulation enhances endogenous analgesic releases [18]. Furthermore, it enhances nitric oxide bioavailability after increased vasodilatation, resulting in improved general endo-neural blood flow and microcirculation systematically, locally, and systemically [19]. It is also plausible to assume that the application of high-frequency electrical stimulation on a muscle ultimately improves its strength resulting in improved spine motor control [20].

Whereas treatment using high frequency may not entirely avoid risk and potentially result in infections that affect life, the RCTs analyzed in this study suggest that the modality is safe and may be used for other chronic pain indications. Unfortunately, in cases where the study duration was short (48 hours or less), the studies reported a recurrence of pain and discomfort. It is still being determined whether the treatment would remain effective over a more extended period; identifying the limitations of high-frequency external muscle stimulation is significant to decide whether continuous treatment would prove more beneficial. Long-term studies are also needed to assess the cumulative impact of HTEMS on the health of people suffering from peripheral neuropathy.

High-tone power therapy has been proven to be more efficient in most aspects, such as reduction in pain intensity and rate of recovery in patients with peripheral neuropathy, compared to other therapy alternatives, such as transcutaneous electrical nerve stimulation. The findings from our study could be replicated in research of future interventions; HTEMS could be integrated as part of a new therapeutic option for patients with peripheral neuropathy from illnesses such as chronic sciatica. Therefore, according to the study's results, high-frequency external muscle stimulation is vital in managing peripheral neuropathy and controlling muscle dysfunction, pain, and function independently.

**Limitations**

This review is limited because of varied fundamental variances among particular findings that emphasis on diverse aspects. For example, few reports focused only on reporting within-group testing and neglecting between-group comparisons. Therefore, in some cases, the analysis was limited by the fact that comparisons among different groups of treatments were not made. Another restraint is the failure to apply to blind patients, therapists, and assessors leading to possible selection bias.

There were some contradicting results in some studies though they were focusing on the same variables. For instance, in some cases, the studies reported the recurrence of some symptoms, while other studies did not report such findings. The contradictions may be attributed to different aspects, including the fact that, in some cases, the duration of treatment using high-frequency external muscle stimulation was too short. Therefore, the findings from the analysis of the studies are subject to scrutiny; they need to accurately depict the true nature of the efficacy of high-frequency external muscle stimulation. In addition, subgroup analysis could not be performed in some cases due to the small number of included studies. Other potentially included researches were also removed due to language constraints are among other limitations.

**Conclusion**

High-tone power therapy has been demonstrated to be very helpful in lowering pain and increasing overall function in people with peripheral neuropathy, with no documented ill effects.

**Author Contributions**

The author and other experts contributed significantly to the systematic review and meta-analysis's design and analysis. They also made meaningful contributions to selecting, screening, and evaluating studies, extracting data and information,
assessing the quality of randomized controlled trials, and synthesizing data. The author was involved in every step of the review and approval of the final manuscript.

Conflicts of Interest

No conflicts of interest were declared.

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https://doi.org/10.1186/s10195-021-00623-6


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Received: 2023-02-19   Accepted: 2023-03-28   In press: 2023-09-23   Published: 2024-06-18