Transcutaneous Electrical Nerve Stimulation for Management of Limb Spasticity
A Systematic Review

ABSTRACT

The purpose of this systematic review was to summarize the effect of transcutaneous electrical nerve stimulation (TENS) for management of limb spasticity. Randomized controlled trials were searched using electronic databases through July 2015. Fourteen randomized controlled trials were included, involving 544 participants.

Intervention protocols fit within three categories: 1) TENS vs. no TENS or placebo TENS (n = 7), 2) TENS vs. another TENS protocol or another intervention for spasticity management (n = 7), and 3) TENS as an adjunct to another intervention for spasticity management (n = 4). There was level 1 and 2 evidence for TENS improving spasticity-related outcome measures within the International Classification of Functioning, Disability, and Health domains of body structure and function (e.g., Modified Ashworth Scale) as well as activity (e.g., gait). Better responses in outcome measures in the International Classification of Functioning, Disability, and Health activity domain were seen when TENS was used in combination with active therapy (e.g., exercise and task-related training) vs. as a single therapeutic modality.

Key Words: muscle spasticity, transcutaneous electric nerve stimulation, electric stimulation therapy, review
Spasticity, a movement disorder that occurs as a result of damage to the central nervous system, is characterized primarily by disinhibited muscle reflexes resulting in intermittent or sustained involuntary muscle activation. Common complications of undertreated spasticity include contractures, pain, skin breakdown, and impaired function. Problematic spasticity has been reported in as many as 40% of individuals with spinal cord injury, 35% with stroke, 53% with cerebral palsy, and 66% with multiple sclerosis despite current management options. Conversely, management options for spasticity are also associated with adverse events. For example, casting for improved range of motion can cause pain and skin breakdown. Commonly used oral medications for muscle relaxation such as baclofen can cause significant systemic side effects including sedation, confusion, nausea, muscle weakness, and liver toxicity. Therefore, there is a need to identify effective interventions to treat spasticity that are well tolerated with acceptable adverse event profiles.

Transcutaneous electrical nerve stimulation (TENS) is a noninvasive modality that can be easily applied by a therapist or trained caregiver or self-applied by the affected individual. TENS excites large diameter A sensory nerve afferents, and there is evidence in the literature that afferent inputs evoked by TENS reach both sensory and motor cortices. There are various hypothesized mechanisms as to how TENS may improve spasticity, including 1) activation of large diameter afferent nerve fibers modulating abnormal interneuron activities in several spinal segments; 2) continuous activation of sensory peripheral nerve fibers resulting in insensitivity to prolonged central excitation, accompanied by lower corticomotor neuron excitability; 3) stimulation of plasticity of the central nervous system; 4) unmasking or reorganization of somatosensory-motor cortical connections; or 5) a combination of the above.

Given that TENS may improve spasticity with a favorable side effect profile, the objective was to conduct a systematic review of randomized controlled trials (RCTs) to provide health care professionals with evidence regarding the efficacy of TENS for the management of limb spasticity in various patient populations. In addition, identifying gaps in the evidence can help direct research efforts to areas of priority.

METHODS

A systematic search developed by the College of Physicians and Surgeons of British Columbia librarians was conducted to identify relevant studies published up to July 15, 2015, using electronic databases MEDLINE (from 1946), EMBASE (from 1974), and Cochrane Central Register of Controlled Trials. An example of the search strategy as applied in MEDLINE can be viewed in the supplemental Table S1, http://links.lww.com/PHM/A170.

The inclusion criteria for this systematic review were RCTs on humans published in the English language. Only RCTs were included because they are subject to less bias than other research designs are. Participants had to have the presence of limb spasticity determined either objectively (e.g., physical exam maneuvers) or subjectively (e.g., self-report). If a subset of the total patients included in a study met inclusion criteria and if the outcomes of the subset were assessed and reported separately, the study was included. The intervention had to be TENS for the purpose of treating spasticity. As electrodes in TENS protocols can be applied to various locations including acupuncture points, muscle bellies, and peripheral nerves, all placement protocols were included in this review as long as stimulation variables matched previously described TENS protocols (e.g., high-frequency, low-frequency, burst, brief intense, or modulated TENS). Study outcomes included objective (e.g., Modified Ashworth Scale, MAS) or subjective (e.g., Penn Spasm Frequency Scale) measures of spasticity, as well as outcomes that can be affected by the presence of spasticity, as categorized by the International Classification of Functioning, Disability, and Health (ICF). The ICF was published by the World Health Organization in May 2001 to provide a common international language for describing health and disability in clinical and research settings. The ICF framework classifies function in four domains: body structure and function (e.g., strength, range of motion, pain), activity (e.g., gait velocity, Timed Up and Go), participation (e.g., employment), and environmental/personal factors.

Two reviewers independently reviewed the studies to determine eligibility for inclusion. Disagreement was resolved through consensus and, if necessary, by third-party resolution. All titles and abstracts were assessed against inclusion criteria. In cases where the abstracts did not give full information for application of criteria, the full-text versions of the studies were reviewed. Reference lists of reviews and relevant studies were retrieved and scanned for citations to expand the data set.

Data were extracted from all included studies independently and in duplicate into an Excel spreadsheet, with the template adapted from the Cochrane...
For all studies, the number of participants, population, intervention, spasticity-related outcomes, and adverse events were extracted. Results were not reported for participants without spasticity.

Two reviewers assessed the methodologic quality of the included studies independently using the Physiotherapy Evidence Database (PEDro) scale. The PEDro scale is composed of 11 yes or no items, 10 of which are used to calculate the final PEDro score (0–10). Using a simplification of the Sackett levels of evidence that has been applied in the literature, an RCT was considered to be level 1 (higher quality evidence) if it scored 6 or higher on the PEDro scale and level 2 if it scored lower than 6.

Owing to the clinically diverse nature of study methods, statistical comparison (meta-analysis) was deemed inappropriate. For example, studies that had the same outcome measures had different durations of and variables for electrical stimulation. Those with the same duration of and variables for electrical stimulation had different outcome measures. Therefore, descriptive comparisons are drawn below. The details and effectiveness of each intervention are outlined in supplemental Tables S2, S3, and S4. As spasticity mechanisms may differ according to whether a lesion occurs in the brain or at the level of the spinal cord, different outcome measures would be appropriate.

RESULTS

Search Strategy

Figure 1 shows the flow of papers into the selected group. Based on inclusion criteria, 14 studies were included.

Studies

Eligible studies ranged in size from 12 to 109 participants, with a total of 544 participants. PEDro scores ranged from 4 to 8, indicating moderate methodologic quality. Six studies had sample size determined by power calculations to detect a meaningful difference. Five studies reported on adverse events.

Participants

Thirteen studies included participants with single etiologies for spasticity including stroke (8 RCTs), spinal cord injury (3 RCTs), and multiple sclerosis (2 RCTs). One study had a mix of etiologies, including multiple sclerosis, spinal cord injury, cerebral palsy, and Strumpell-Lorrain degenerative disease. One study had a subjective measure of spasticity as a participant inclusion criterion (e.g., self-reported presence of problematic spasticity resulting in pain, interfering with activities of daily living, or both). All other studies had objective measures of spasticity as participant inclusion criteria (e.g., presence of spasticity documented on MAS). No studies that met inclusion criteria were conducted on participants younger than 18 yrs.

Interventions

Intervention protocols within the 14 studies fit within three categories: 1) TENS for spasticity management vs. no intervention or placebo TENS ($n = 7$), 2) a TENS protocol for spasticity management vs. either another TENS protocol for spasticity management or a non-TENS intervention for spasticity management ($n = 7$), and 3) TENS as an adjunct to another intervention for spasticity management (i.e., spasticity intervention + TENS) ($n = 4$). Two studies had protocols that fit in two or more of these categories.

The number and duration of TENS sessions varied between studies. The shortest intervention investigated was one session of TENS, and the longest intervention was five sessions of TENS per week over 3 mos. All studies investigated interventions to the spastic lower limb, except for Sonde et al., in which spasticity of the upper limb in individuals with stroke was investigated. Most studies used TENS parameters of frequency between 99 and 100 Hz, pulse width between 0.06 and 0.2 msec, intensity 1 to 3 times the sensory threshold, or 15 to 50 mA. The exceptions to these TENS settings were Sonde et al., in which a frequency of 1.7 Hz was used, and Frasson et al., in which frequencies of 4 and 25 Hz were used. TENS was mostly provided at a submotor level of stimulation.

Adverse Events

Five studies reported on adverse events. In the study by Ping Ho Chung and Kam Kwan Cheng, 3 of the 10 participants receiving a single session of 60 mins of TENS at 100 Hz, 0.25 msec pulse width, and 15 mA intensity experienced transient (<1 hr) mild skin irritation with erythema that resolved spontaneously. This was the only study that had adverse events with TENS. Ng and Hui Chan reported no adverse events in 55 participants who received 20 sessions of 60 mins of TENS at 100 Hz,
0.2 msec, pulse width, and intensity at 2 times sensory threshold. Shaygannejad et al.\textsuperscript{29} reported 4 dropouts out of 26 participants in the Baclofen group because of severe drowsiness and gastrointestinal effects. Aydin et al.\textsuperscript{31} reported 5 of 21 participants in the Baclofen group experiencing adverse events (dry mouth and fatigue), but none dropped out of the study.

<table>
<thead>
<tr>
<th>TABLE 1 Levels of evidence of TENS for management of limb spasticity</th>
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<td><strong>Level of Evidence</strong></td>
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Results, Category 1: TENS vs. Placebo or no TENS

Stroke

Of the seven studies comparing TENS for spasticity with no intervention or placebo TENS, six\textsuperscript{25-27,32,35,36} were on participants with stroke. Stroke duration ranged from 6 mos to 4 yrs with number and duration of TENS sessions varying among studies (see Table S2).

In a powered, level 2 (PEDro ≤ 6) placebo-controlled RCT\textsuperscript{27}, a single 60-min session of TENS was found to immediately improve outcomes in the ICF body structure and function as well as activity domains, with improved MAS and standing balance with eyes closed on a stable surface, but not with eyes open on a stable or unstable surface.

A nonpowered, level 2 placebo-controlled RCT\textsuperscript{36} investigating 15 sessions of 60 mins of TENS over 3 wks demonstrated improvement in outcomes of ICF body structure and function domain including Clinical Spasticity Score, vibratory inhibition of the soleus H reflex, stretch reflex excitability, and dorsiflexion strength.

Two high-quality, level 1 (PEDro ≥ 6) but non–placebo-controlled RCTs\textsuperscript{25,26} investigating
20 sessions of TENS over 4 wks with the same TENS settings demonstrated improvement in outcome measures of body structure and function, including Composite Spasticity Score and peak torque of ankle dorsiflexor, but not peak torque of ankle plantarflexors. Results for outcome measures in the ICF activity domain were generally not positive, with no significant differences between groups in gait velocity and 6-min walk test. Timed Up and Go improved immediately after the TENS sessions vs. the no TENS group, but improvements did not persist after 4 wks of follow-up after the intervention.

The RCT by Sonde et al. in 2000\textsuperscript{32} was a 3-yr follow-up to the level 2, nonpowered, and non–placebo-controlled RCT by Sonde et al. in 1998;\textsuperscript{35} where a low frequency of 1.7 Hz was used. Immediately after 60 sessions of 60 mins of low-frequency TENS delivered to the upper extremity over 3 mos, arm activity as measured by the Fugl-Meyer Motor Performance Scale improved in the TENS vs. no TENS group. Patients with moderate function (Fugl-Meyer score 30–50) and shortest post-stroke time had best outcomes. This improvement was not sustained at 3-yrs follow-up, during which no TENS was delivered. There were no improvements in the other outcome measures in the ICF body structure and function (MAS, spasticity visual analog scale, pain visual analog scale) and activity (Barthel Index) domains at any time points.

Spinal Cord Injury

The only study\textsuperscript{28} in this category on participants with spinal cord injury was a powered, placebo-controlled high-quality double blinded RCT. A single 60-min session of TENS over the common peroneal nerve of the limb with dominant spasticity demonstrated improvement in outcome measures in the ICF body structure and function domain including the Composite Spasticity Scale and resistance to passive ankle dorsiflexion, but not ankle clonus or Achilles tendon jerks.

Results, Category 2: TENS vs. Either Another TENS Protocol for Spasticity Management or a Non-TENS Intervention for Spasticity Management

Stroke

Of the seven studies comparing TENS for spasticity with another TENS protocol or another spasticity management intervention, three,\textsuperscript{25,26,34} were on participants with stroke greater than 6 mos’ duration. A high-quality, nonpowered, and non–placebo-controlled RCT\textsuperscript{25} compared 20 sessions of 60 mins of TENS over 4 wks to an equivalent frequency and duration of exercise sessions focused on the lower limbs (see Table S3). Exercise was equivalent to TENS for outcome measures in the ICF activity domain, including gait velocity and 6-min Walk Test. Exercise was better than TENS for Timed Up and Go, even at the 4-wk follow-up after the interventions were completed.

Another high-quality, nonpowered, non–placebo-controlled RCT\textsuperscript{29} compared 20 sessions of 60 mins of TENS over 4 wks to an equivalent frequency and duration of task-related training. Task-related training included weight-bearing, stepping, sit-to-stand, and walking exercises. Short-term improvements were seen in most of the outcome measures in the ICF body structure and function domain but not in the activity domain. When half of the sessions were completed (at 2 wks), the TENS vs. task-related training group had improvements in the Composite Spasticity Scale, but the between-group difference did not persist immediately after the sessions and at the 4-wk follow-up. Peak torque of the dorsiflexors improved for the TENS vs. task-related training group at 2 wks and immediately after intervention but did not persist at 8 wks. There were no between-group differences for peak torque of the plantarflexors or gait velocity.

A nonpowered level 2 RCT\textsuperscript{34} comparing a single 30-min session of TENS to the same duration of cryotherapy demonstrated that outcome measures in the ICF body structure and activity domain as measured by electrodiagnostics (e.g., H-reflex variables) were improved after TENS and unchanged or worsened after cryotherapy.

Multiple Sclerosis

Two\textsuperscript{29,33} studies investigated participants with multiple sclerosis. One level 2, nonpowered randomized crossover trial\textsuperscript{33} compared two different TENS protocols with the same variable settings but different durations (60 mins/day vs. 8 hrs/day over 2 wks, delivered while participants performed usual activities of daily living). Outcome measures in the ICF body structure and function domain, Penn Spasm Score, and pain visual analog scale improved in the 8 hrs vs. the 60 mins per day group, with no significant differences in the Global Spasticity Score. Most participants (73.3%–87.5%) had subjective improvements in spasms, pain, and stiffness. On follow-up (8–20 mos after completion of study), most participants were still using TENS, mainly on an “as required” basis, for variable application durations from 60 mins to 8 hrs.

The other study on multiple sclerosis participants was a powered, nonblinded level 2 RCT.\textsuperscript{29}
TENS delivered at least 20 to 30 mins/day over 4 wks, supplemented by application whenever there were any muscle spasms as determined by the participant, was compared to baclofen (see Table S3 for baclofen therapy details). MAS, the only outcome measure, was significantly improved in the TENS vs. baclofen group immediately after the interventions. The baclofen group had three dropouts due to severe drowsiness and one dropout due to dizziness and gastrointestinal effects.

**Spinal Cord Injury**

One study\(^{31}\) on participants with spinal cord injury compared TENS with baclofen. This nonpowered, level 2 RCT demonstrated equivalence in all outcome measures (ICF body structure and function and activity domains) with 15 daily consecutive sessions of 15 mins of TENS over the tibial nerve vs. baclofen (see Table S3 for details). Both TENS and baclofen had significant within-group differences for MAS, Penn Spasm Score, deep tendon reflex score, functional disability score, and Functional Independence Measure, but not Hmax/Mmax ratio, H-reflex latency, clonus score, and plantar stimulation response score.

**Mixed Spasticity Etiology**

One high-quality, nonpowered RCT\(^ {30}\) compared two different TENS protocols (high frequency, 25 Hz, vs. low frequency, 4 Hz). Both TENS protocols were performed in addition to botulinum neurotoxin injections (same injection protocol) of the extensor digitorum brevis in participants with mixed spasticity etiology. There were improvements in compound muscle action potential percentage reductions for certain time points after injection with low-frequency TENS and no changes with high-frequency TENS. Electromyographic signs of denervation appeared earlier in stimulated muscles compared with nonstimulated muscles. MAS did not change in any of the participants throughout follow-up.

**Results, Category 3: TENS as an Adjunct Therapy to Another Spasticity Management Intervention**

**Stroke**

The three studies\(^ {25,26,37}\) in this category investigated participants at least 6 mos after stroke (see Table S4). All studies demonstrated significant differences in improvements in outcomes in the ICF activity domain (gait parameters\(^ {25,26,37}\) and Timed Up and Go\(^ {25,37}\)) when TENS was delivered as an adjunct therapy during or after each session of exercise or task-related therapy. In the two studies with longer-term follow-up, these differences persisted after 4 wks with no interventions\(^ {25,26}\). Results for outcomes in the ICF body structure and function domain (peak torque ankle dorsiflexion and Composite Spasticity Scale) were not as positive, with differences in improvements seen halfway through intervention but not maintained immediately after or on follow-up.\(^ {26}\) Between-group differences were not seen for the 6-min walk test\(^ {25}\) or peak torque ankle plantarflexion.\(^ {26}\)

**Spinal Cord Injury**

One high-quality, powered RCT\(^ {38}\) on participants with chronic spinal cord injury and lower extremity spasticity demonstrated that addition of 60 mins of TENS before 15 sessions of standardized physical therapy interventions improved immediate and short-term Composite Spasticity Scale scores compared with physical therapy alone. Physical therapy was provided by a trained physiotherapist with a focus on strength, range of motion, dexterity, and functional skills.

**DISCUSSION**

Overall, results were variable when TENS was used alone but more consistently showed improvement, particularly for outcome measures in the ICF activity domain, when TENS was used as an adjunct therapy in combination with active therapy for management of spasticity (e.g., exercise and task-related training). Comparison of TENS with other spasticity interventions suggests that TENS is equivalent to or better than baclofen and task-related training, equivalent or inferior to exercise, and superior to cryotherapy. Comparison of different TENS protocols suggests that longer durations of TENS sessions are better than shorter durations (with frequency settings of 100 Hz) and that low-frequency TENS at 4 Hz is better than high-frequency setting at 25 Hz. Study results also suggest that improvements occur during or for a short period of time after TENS alone is delivered but may not persist after TENS is discontinued\(^ {25,32}\) unless delivered as an adjunct to active therapy.\(^ {25,26}\)

The application of sensory-level electrical stimulation to modify spasticity is currently used only in a limited manner; thus, this review provides moderately strong evidence to support the use of TENS for patients with limb spasticity and can advance evidence-based practice in this area. Most systematic reviews are organized primarily by diagnosis, whereas this review offers a unique way to organize the information by categorizing three general treatment approaches. Thus, the review permits the reader to think about the effectiveness of a given treatment approach.
approach within the context of each of several neurologic diagnoses with which spasticity is associated.

There is a need for further research into all TENS interventions as most results are based on single RCTs. However, it is important for clinicians to be knowledgeable regarding the current levels of evidence relevant to their practice, even if independent replication of evidence is lacking. This review is also useful for investigators, as results highlight the need for future research to be conducted in this area. Recommendations for future studies are provided below.

TENS was found to be a safe intervention with no significant adverse events reported with short-term use, although adverse events were only reported in 5 of the 14 studies. Given that improvements related to TENS seem to decline once TENS is discontinued, a clinical question that merits further research is whether long-term TENS stimulation is safe (e.g., potential for damage to peripheral nerves) and continues to be effective over years of use, as the presence of spasticity usually persists over the long-term. One RCT\textsuperscript{33} reported that on follow-up of up to 20 mos after completion of the study, most participants were still using TENS, mainly on an “as required” basis, for variable application durations from 60 mins to 8 hrs. Unfortunately, adverse events in this subset of participants were not reported.

Studies in this review did not consider how intervention affected participation in the community, and no RCTs examined effects on quality of life, although these domains have been shown to be negatively impacted in individuals with spasticity.\textsuperscript{39,40} Therefore, these types of outcome measures should be included in future studies.

Sites of electrode placement differed among studies, with sites including acupuncture points, dermatomes, muscle bellies, and peripheral nerves. It is not yet known whether location of electrode placement or other variables within the TENS protocol such as pulse width, frequency, and intensity influence spasticity outcomes. Further exploration of optimal stimulation parameters is still required to provide the paramount benefits for individuals with limb spasticity patients.

Despite various stated hypotheses in the literature, the mechanisms by which TENS could be exerting its effects on spasticity and movement control remain unclear. Given that the mechanisms of spasticity differ according to lesion location (e.g., brain vs. spinal lesions) and can result in different spasticity patterns,\textsuperscript{24,41} it is important for future studies to maintain homogenous participant study populations when investigating the effects of TENS. The strength of this review’s findings is limited by inability to perform a meta-analysis on the results because of the heterogeneity of study methods. Articles reviewed were limited to English, and although the search strategy to identify studies for this review was comprehensive, given the broad nature of the topic reviewed, it is possible that some studies may have been missed.

**CONCLUSION**

The current review provides analysis of the effectiveness of TENS for the management of limb spasticity. Given that TENS is a relatively safe intervention with an acceptable adverse event profile and that there is level 1 and 2 evidence for its short-term effectiveness in the management of spasticity in various neurologic etiologies, clinicians can consider using TENS as an adjunct therapy to limb spasticity management. Further research into TENS for management of limb spasticity including independent replication of results is warranted.

**ACKNOWLEDGMENTS**

The authors thank Felicia Wong, BKin, for assisting with third-party resolution during the application of eligibility criteria for study inclusion in this review.

**Supplementary Checklist**

PRISMA Checklist: http://links.lww.com/PHM/A174

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