

# Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review)

Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology



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## ABSTRACT

**Objective:** To determine if transcutaneous electric nerve stimulation (TENS) is efficacious in the treatment of pain in neurologic disorders.

**Methods:** We performed a systematic literature search of Medline and the Cochrane Library from inception to April 2009.

**Results:** There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain, with 2 Class II studies showing benefit, but 2 Class I studies and another Class II study not showing benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic low back pain (2 Class I studies). TENS is probably effective in treating painful diabetic neuropathy (2 Class II studies).

**Recommendations:** Transcutaneous electric nerve stimulation (TENS) is not recommended for the treatment of chronic low back pain (Level A). TENS should be considered in the treatment of painful diabetic neuropathy (Level B). Further research into the mechanism of action of TENS is needed, as well as more rigorous studies for determination of efficacy. *Neurology*® 2010;74:173–176

## GLOSSARY

CI = confidence interval; TENS = transcutaneous electric nerve stimulation; TENS-burst = burst-pattern TENS; TENS-FM = frequency-modulated TENS; VAS = visual analog scale.

Transcutaneous electric nerve stimulation (TENS) has been used in the treatment of neurologic and other disorders for the last several decades. The biologic basis of the analgesic effect of TENS is not known, but the rationale for the use of TENS is based on the gate theory of pain.<sup>1</sup> TENS is used extensively for pain relief in various disorders.

TENS is the application of a mild electrical current to the cutaneous nerve fibers using surface electrodes. The stimulation is characterized by current, pulse width, and changes in frequency, though in some paradigms a stochastic or quasi-random stimulation frequency is used. The amplitude of the current is usually adjusted to just above or just below the sensory threshold. Duration of application varies from short time periods (e.g., 30 minutes) once to continuous stimulation. Duration of treatment can be days to months.

A fundamental question in any therapeutic trial is whether adequate blinding can be maintained for the intervention. In a study of TENS-naïve participants with chronic low back pain, TENS was compared to sham TENS (TENS-sham; in this case a nonfunctioning unit identical to the TENS unit with a light flashing at the stimulus frequency indicating that the unit was “on”). The blinding was mostly successful, with 100% of the TENS group and 84% of the TENS-sham group identifying their unit as working, though with a lesser degree of conviction in the TENS-sham group.<sup>2</sup>

This assessment summarizes evidence on the efficacy of TENS in the treatment of pain, specifically the pain associated with neurologic disorders.

## DESCRIPTION OF THE ANALYTIC PROCESS

We performed a Medline search from inception to April 2009, using the terms “transcutaneous electric

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Appendices e-1 through e-4 and table e-1 are available on the *Neurology*® Web site at [www.neurology.org](http://www.neurology.org).

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nerve stimulation” (MeSH) and “nervous system diseases” (MeSH) or “peripheral nervous system diseases” (MeSH) or “central nervous system diseases” (MeSH), which was limited to “clinical trial, meta-analysis, practice guideline, randomized controlled trial, human.” The Cochrane Library was searched using the terms “transcutaneous electric nerve stimulation” or “TENS.” Inclusion criteria were clinical trials of TENS compared to placebo or to another therapy for well-defined painful neurologic disorders with more than 10 subjects. The titles and abstracts were reviewed, and articles meeting criteria were reviewed in full and assigned a class of evidence (appendix e-3). Recommendations were based on the level of evidence (appendix e-4). Disagreement about the assigned level of evidence was resolved through discussion. Additional articles were obtained from the bibliographies of these articles and of review articles.

We adopted the definitions used in each paper for meaningful reduction in pain, realizing that this varies between treatments for acute and for chronic pain. In 2 studies of patients presenting to emergency departments with acute onset or worsening of pain, the patient self-determined minimum significant change in pain (i.e., a little bit worse, a little bit better) correlated with a mean change in visual analog scale (VAS) of  $\pm 13$  mm (95% confidence interval [CI] 10–16) in trauma patients and  $\pm 9$  mm (95% CI 6–13) in a mixed population of trauma and nontrauma patients.<sup>3,4</sup> Although the World Health Organization classifies significant pain reduction in the treatment of patients with cancer as >50% using a 100 mm VAS or a decrease to a level of 3 or less using a verbal rating scale of pain intensity from 0 to 10, the definition of meaningful pain reduction is controversial. Thus, many of the articles used a decrease of 20 mm or a 25% decrease with a baseline VAS of 50 mm or less as clinically significant.

**ANALYSIS OF THE EVIDENCE** The primary and secondary searches yielded 263 articles. Eleven studies met the inclusion criteria (table e-1). Two studies of chronic pain were excluded because etiologies of pain were diverse and meaningful data on any one type of pain could not be extracted from presented data.

**Low back pain.** There were 2 Class I studies and 3 Class II studies evaluating the efficacy of TENS in the treatment of low back pain of various etiologies (some diagnoses were readily accepted as neurologic illness, while others may be controversial; however, all patients experienced low back pain for at least 3 months). The Class I studies compared TENS to

TENS-sham in the treatment of chronic low back pain with the duration of treatment either 4 or 6 weeks.<sup>5,6</sup> In one study, a  $2 \times 2$  factorial design was used to compare TENS, TENS-sham, exercise, and no exercise. No benefit was found for TENS compared to TENS-sham using a VAS and other outcome measures, but benefit was found comparing exercise to no exercise.<sup>5</sup> In the other Class I study, TENS vs TENS-sham was studied in patients with multiple sclerosis (MS) and chronic low back pain. After correction for multiple comparisons, there were no significant differences in the VAS or the secondary measures.<sup>6</sup> Both studies were adequately powered to find at least a 20% difference in pain reduction by VAS between TENS and TENS-sham.

A Class II study compared different TENS modalities in a randomized 3-session trial. Although various diagnoses were included (including non-low back pain), sufficient data were presented to allow review of the low back pain data. Conventional TENS, frequency-modulated TENS (TENS-FM), and burst-pattern TENS (TENS-burst) were assessed with a VAS compared to baseline after a single 30-minute session. Benefit was reported in 8/11 patients who had TENS-FM, 4/11 who had TENS-burst, and 1/11 who had conventional TENS. One subject did not have benefit with any modality.<sup>7</sup> In a study comparing TENS and TENS-sham to a control group, a modest benefit in pain reduction (15 mm or greater decrease on a VAS compared to baseline) was seen after 1 and after 10 weeks of therapy, but not for the unpleasantness of pain.<sup>8</sup> This study excluded patients with scoliosis greater than 15 degrees, spondylolisthesis, surgical lesions, vertebral compression fractures, and obesity. The benefit continued to 3 and 6 months after completion of TENS or TENS-sham with no difference between the 2 treatments. The last Class II study examined the benefit of TENS compared to TENS-sham for patients with MS and low back pain. After correction for multiple comparisons, no significant differences were found.<sup>9</sup>

**Conclusions.** There was conflicting evidence for the use of TENS for chronic low back pain. In 2 Class I studies adequately powered to detect a 20% difference in the proportion of patients with benefit, no benefit was found. Two Class II studies demonstrated a modest benefit, while a third Class II study did not demonstrate benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic low back pain.

**Painful diabetic distal symmetric polyneuropathy.** Two Class II studies compared TENS to TENS-sham, and 1 Class III study compared high-frequency muscle stimulation to TENS in the relief of pain associated

with mild diabetic peripheral neuropathy (distal symmetric neuropathy, excluding patients with mononeuropathies and plexopathies).<sup>10–12</sup> A modest reduction in VAS was found for TENS compared to TENS-sham, and a larger proportion felt benefit with the high-frequency muscle stimulation compared to TENS.

**Conclusion.** On the basis of 2 Class II studies, TENS is probably effective in reducing pain from diabetic peripheral neuropathy.

**Clinical context.** Many treatment options are commonly used for diabetic neuropathy, but there are presently no comparative studies of TENS to other treatment options.

## RECOMMENDATIONS

1. TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, 2 Class I studies).
2. TENS should be considered for the treatment of painful diabetic neuropathy (Level B, 2 Class II studies).

## RECOMMENDATIONS FOR FUTURE RESEARCH

For such a widely used therapeutic modality, the evidence for the efficacy of TENS in treating pain associated with neurologic disorders is meager.

1. Studies should be performed on TENS-naïve subjects, when possible.
2. The optimal paradigm of TENS for alleviation of induced pain needs to be determined and then applied to painful disorders.
3. Once the optimal paradigm is established, future studies of the efficacy of TENS should be randomized controlled clinical trials of TENS compared to TENS-sham, rather than comparison of different TENS paradigms or untreated controls. These studies should utilize TENS for chronic therapy, rather than single sessions; have an adequate number of subjects with well-defined painful conditions; and be directed toward common painful neurologic conditions.
4. Other pain syndromes, such as posttraumatic nerve injuries, should have the same rigorous methodologies applied to determine the efficacy of TENS.

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## DISCLOSURE

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CAM #2007P000827 (Site Investigator), NCCAM UO1AT000613 (Site Investigator)]; and his spouse owns stock in Abbott. Dr. Miyasaki has served on a scientific advisory board for Teva Pharmaceutical Industries Ltd.; has received honoraria for educational activities not funded by industry; serves on the editorial board of *Movement Disorders*; has received speaker honoraria from Biovail Corporation; serves/has served as a consultant to Janssen-Ortho, Inc., Merz Pharmaceuticals GmbH, Schering-Plough Corp., the NIH (Independent Medical Monitor), Ontario Drug Benefits, and Common Drug Review, Canada; and receives research support from Teva Pharmaceutical Industries Ltd., Boehringer Ingelheim, Solvay Pharmaceuticals, Inc., Solstice Neurosciences, Inc., Impax Laboratories, Neurogen, Medivation, Inc., the National Parkinson Foundation, the Parkinson Society Canada, the Michael J. Fox Foundation, and the Huntington Study Group.

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## CONFLICT OF INTEREST

The American Academy of Neurology is committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, a network of neurologists, *Neurology*<sup>®</sup> peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at [www.aan.com](http://www.aan.com).

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