



## Complete Summary

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### GUIDELINE TITLE

Clinical practice guidelines for transcutaneous electrical nerve stimulation (TENS).

### BIBLIOGRAPHIC SOURCE(S)

Brosseau L, Wells GA, Finestone HM, Egan M, Dubouloz CJ, Graham I, Casimiro L, Robinson VA, Bilodeau M, McGowan J. Clinical practice guidelines for transcutaneous electrical nerve stimulation (TENS). *Top Stroke Rehabil* 2006 Spring;13(2):61-3.

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Hemiplegia or hemiparesis following a single clinically identifiable ischemic or hemorrhagic cerebrovascular accident (CVA)

### GUIDELINE CATEGORY

Management  
Rehabilitation

### CLINICAL SPECIALTY

Neurology  
Physical Medicine and Rehabilitation

## **INTENDED USERS**

Occupational Therapists  
Patients  
Physical Therapists  
Physicians  
Students

## **GUIDELINE OBJECTIVE(S)**

To promote the appropriate use of various rehabilitation interventions in the management of stroke survivors

## **TARGET POPULATION**

Adult patients (>18 years of age) presenting with hemiplegia or hemiparesis following a single clinically identifiable ischemic or hemorrhagic cerebrovascular accident (CVA)

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Transcutaneous electrical nerve stimulation (TENS) (low- or high-intensity)

**Note:** See the "Major Recommendations" field and the original guideline document for specific recommendations for individual interventions.

## **MAJOR OUTCOMES CONSIDERED**

- Body function: pain reduction, muscle strength, motor function/motor recovery, range of motion (ROM), postural status, balance status, gait status, cadence, stride length, sensory status, spasticity/muscle tone, global physician assessment, global patient assessment, and cardiopulmonary function.
- Activities and participation: walking speed, walking distance, endurance, functional status, patient adherence, patient satisfaction, length of stay, discharge disposition, quality of life, and return to work.

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

#### **Literature Search**

The library scientist developed a structured literature search based on the sensitive search strategy recommended by The Cochrane Collaboration and modifications to that strategy proposed by Haynes et al\*. The Cochrane

Collaboration method minimizes bias through a quantitative systematic Weighted Mean Difference approach to the literature search, study selection, and data extraction and synthesis. The search was organized around the condition and interventions rather than the outcomes because it was an a priori search. Thus, the guideline developers had no control over the outcomes that the authors of the primary studies decided to measure (See Appendix 1 in the original guideline document for literature search results).

The library scientist expanded the search strategy to identify case control, cohort, and non-randomized studies and conducted the search in the electronic databases of MEDLINE, EMBASE, Current Contents, the Cumulative Index to Nursing and Allied Health (CINAHL), and the Cochrane Controlled Trials Register up to December 2004. She also searched the registries of the Cochrane Field of Rehabilitation and Related Therapies, the Cochrane Musculoskeletal Group, the Physiotherapy Evidence Database (PEDro), and the University of Ottawa EBCPGs Web site. Finally, she searched the reference lists of all of the included trials for relevant studies and contacted content experts for additional studies.

In the first round of study inclusion or exclusion, two trained independent reviewers appraised the titles and abstracts of the literature search, using a checklist with the a priori defined selection criteria (Table 1 in the original guideline document). For each pair of reviewers, individuals independently read the title and abstract of each article and created a list of all of the articles in the database along with a reason for either including or excluding each article. If the reviewers were uncertain about a particular article after having read the abstract, they ordered the article and read it in full before making a determination. Before deciding whether to include or exclude the article, a comparison of their individual lists was performed. A senior reviewer, a methodologist and a clinical expert, checked the two independent lists of articles and the reasons for inclusion or exclusion to determine potential inconsistencies. Seven percent of the abstracts needed the consultation of the senior reviewer and an additional review of the problematic article. For the second round of the inclusion and exclusion process, the pairs of reviewers retrieved articles selected for inclusion from the first round and independently assessed the full articles for inclusion or exclusion in the study. Using predetermined extraction forms, the pairs of reviewers independently extracted from included articles data on the population characteristics, details of the interventions, trial design, allocation concealment, and outcomes. The pairs of reviewers assessed the methodological quality of the studies using the Jadad Scale a 5-point scale with reported reliability and validity that assigns 2 points each for randomization and double blinding and 1 point for description of withdrawals. The reviewers resolved differences in data extraction and quality assessment through consensus with the senior reviewer. This consensus served to support the reliability of data obtained with the article selection process.

### **Study Inclusion/Exclusion Criteria**

The inclusion/exclusion criteria were based upon previous criteria used by the Philadelphia Panel. This list of criteria, which had been created for multiple diagnoses, was adapted and approved by the Ottawa Methods Group (OMG) for use with patients post stroke (Table 1 in the original guideline document).

All original comparative controlled studies that evaluated relevant physical rehabilitation interventions in stroke patients were included: randomized controlled trials (RCTs), controlled clinical trials (CCTs),\*\* cohort studies, and case-control studies. Crossover studies were included, but to avoid potential confounding carry-over effects the data from only the first part of the study (before crossing) was analyzed. Studies where patients served as their own controls were excluded. No limitations based on methodological quality were imposed a priori with regard to the selection of comparative controlled studies; however, the quality of the studies was considered when grading the recommendations resulting from our analysis.

Uncontrolled cohort studies (studies with no comparison group) and case series were excluded, as were eligible studies with greater than a 20% drop-out rate or a sample size of fewer than 5 patients per group. Trials published in languages other than French and English were not analyzed, because of the additional time and resources required for translation. Abstracts were excluded if they contained insufficient data for analysis and additional information could not be obtained from the authors. For further exclusion criteria, see Table 1 in the original guideline document.

\*Haynes R, Wilczynski N, McKibbon KA, Walker CJ. Developing optimal search strategies for detecting clinically sound studies in MEDLINE. *J Am Med Inform Assoc.* 1994;1:447-458.

\*\*Controlled clinical trials (CCTs) are considered the same as randomized control trials (RCTs). However, according to the Jadad Scale, CCTs are either not randomized or have not been appropriately randomized.

## **NUMBER OF SOURCE DOCUMENTS**

6 articles were included.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus (Committee)  
Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

**Level I:** Randomized controlled trials

**Level II:** Nonrandomized studies

## **METHODS USED TO ANALYZE THE EVIDENCE**

Meta-Analysis of Randomized Controlled Trials  
Review of Published Meta-Analyses

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

The data were analyzed using Review Manager Software. Continuous data, "data with a potentially infinite number of possible values along a continuum," were

analyzed using the weighted mean differences (WMDs) between the intervention and control groups at the end of the study, where the weight is the inverse of the variance. A WMD is "a method of meta-analysis used to combine measures on continuous scales (such as weight), where the mean, standard deviation and sample size in each group are known." Dichotomous data or data with only two classifications were analyzed using relative risks. According to Cochrane, the relative risk is "the ratio of risk in the intervention group to the risk in the control group. The risk (proportion, probability, or rate) is the ratio of people with an event in a group to the total in the group."

See the original guideline document for more information.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

### **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

The research staff reviewed articles and created draft evidence tables, which the nine clinical experts received in preparation for their consensus meeting with the Ottawa Methods Group (OMG). These tables were used as the basis for making the Ottawa Panel recommendations.

A methods group developed the draft guidelines and they were adopted by expert consensus.

### **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

**Grade A:** Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit (>15%)

**Grade B:** Statistically significant, clinically important benefit (>15%), if the evidence was from observational studies or controlled clinical trials (CCTs)

**Grade C+:** Evidence of clinical importance (>15%) but not statistical significance

**Grade C:** Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown

**Grade D:** Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group (<0%: favors controls)

**Grade D+:** Evidence of clinical importance ( $\leq$ -15% for controls) without statistical significance

**Grade D-:** Evidence from one or more randomized controlled trials of a clinically important benefit ( $\leq$ -15% for controls) that was statistically significant, where the number of participants in the study is equal to or higher than 100

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guidelines were sent to the external experts for review. To judge the clinical usefulness of the guidelines, the positive recommendations were also sent to practitioners for feedback. Practitioners were asked four questions for each guideline: whether the recommendation was clear, whether the practitioners agreed with the recommendation, whether they felt that the literature search on the different intervention of rehabilitation was relevant and complete, and whether the results of the trials in the guidelines were interpreted according to the practitioners' understanding of the data. Their questions and comments were carefully addressed to improve the clarity of the final guidelines.

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

The recommendations are graded by their level (I, II) and strength (A, B, C+, C, D, D+, D-) of evidence. Definitions for the level and strength of the recommendations are presented at the end of the "Major Recommendations" field.

#### **Clinical Practice Guidelines for Transcutaneous Electrical Nerve Stimulation (TENS)**

**Low-intensity TENS applied to lower extremity versus placebo**, level I (randomized controlled trial [RCT]): **Grade A** for decrease in spasticity for lower extremity at end of treatment, 2 and 3 weeks (clinically important benefit demonstrated); **grade C+** for dorsiflexor strength at end of treatment, 3 weeks (clinically important benefit demonstrated, without statistical significance). Patients with chronic stroke.

**Low-intensity TENS applied to the elbow and ankle versus placebo**, level I (RCT): **Grade A** for functional status at end of treatment, 8 weeks (clinically important benefit demonstrated). Patients with post-acute stroke.

**Low-intensity TENS applied to the shoulder versus placebo**, level I (RCT): **Grade C** for passive shoulder range of motion (ROM) at end of treatment, 4 weeks, and at follow-up, 4 weeks (no benefit demonstrated). Patients with post-acute stroke.

**Low-intensity TENS applied to the upper extremity versus control**, level I (RCT): **Grade C** for motor function (Fugl-Meyer) and functional status at end of treatment, 3 months, and follow-up, 3 years, as well as motor function (change in Fugl-Meyer) and decrease in spasticity (elbow flexors) at end of treatment, 3 months (no benefit was demonstrated); **grade D+** for decrease in spasticity (wrist flexors) at follow-up, 3 years (clinically important benefit favoring control, demonstrated without statistical significance); **grade D** for decrease in spasticity (wrist flexors) at end of treatment, 3 months. Patients with chronic stroke.

**High-intensity TENS applied to the shoulder versus placebo**, level 1 (RCT): **Grade A** for passive shoulder ROM at end of treatment, 4 weeks, and follow-up, 4 weeks (clinically important benefit demonstrated). Patients with post-acute stroke.

**High-intensity TENS versus low-intensity TENS applied to the shoulder**, level I (RCT): **Grade A** for passive shoulder ROM (extension, abduction, external rotation) at end of treatment, 4 weeks, and follow-up, 4 weeks, and passive shoulder ROM (flexion) at follow up, 4 weeks (clinically important benefit demonstrated); **grade C** for passive shoulder ROM (flexion) at end of treatment, 4 weeks (no benefit demonstrated). Patients with post-acute stroke.

**Low-intensity TENS applied to the hand versus placebo**, level II (controlled clinical trial [CCT]): **Grade B** for sensation at end of treatment, 3 weeks (clinically important benefit demonstrated); **grade C** for motor function and gait speed at end of treatment, 3 weeks (no benefit demonstrated). Patients with chronic stroke.

**Low-intensity TENS applied to the foot versus placebo**, level II (controlled clinical trial): **Grade B** for sensation at end of treatment, 3 weeks (clinically important benefit demonstrated); **grade C** for motor function and gait speed at end of treatment, 3 weeks (no benefit demonstrated). Patients with chronic stroke.

### **Definitions:**

#### **Level of Evidence**

**Level I:** Randomized controlled trials

**Level II:** Nonrandomized studies

#### **Grade of Recommendation**

**Grade A:** Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit (>15%)

**Grade B:** Statistically significant, clinically important benefit (>15%), if the evidence was from observational studies or controlled clinical trials (CCTs)

**Grade C+:** Evidence of clinical importance (>15%) but not statistical significance

**Grade C:** Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown

**Grade D:** Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group (<0%: favors controls)

**Grade D+:** Evidence of clinical importance ( $\leq$ -15% for controls) without statistical significance

**Grade D-:** Evidence from one or more randomized controlled trials of a clinically important benefit ( $\leq$ -15% for controls) that was statistically significant, where the number of participants in the study is equal to or higher than 100

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is specifically stated for each recommendation.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Post-stroke physical rehabilitation interventions have been used to reduce pain and spasticity, as well as to increase range of motion (ROM), muscle force, mobility, walking ability, functional status, physical fitness, and quality of life. Post-stroke physical rehabilitation interventions are mostly noninvasive interventions that present very few adverse side effects and contraindications as compared with a large number of pharmacologic interventions.

### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

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jointly adopted by a Committee of the American Bar Association and a Committee of Publishers and Associations.)

Drug and dosage selection: The authors have exerted every effort to ensure that drug selection and dosage set forth in this text are in accord with recommendations and practice current at the time of publication. However, we suggest that appropriate information sources be consulted when dealing with new and unfamiliar drugs. It remains the responsibility of every practitioner to evaluate the appropriateness of a particular opinion in the context of the actual clinical situation and with due consideration to any new developments in the field.

## **Limitations**

It is important to point out that the Ottawa Panel Evidence-Based Clinical Practice Guidelines (EBCPGs) are not without limitations. First of all, the strength of clinical practice guidelines depends upon the quality of the primary studies found in the literature. The clinical studies that met the Ottawa Panel's selection criteria rarely exceeded 3 out of 5 on the Jadad scale, and the sample sizes were generally small. These methodological issues limit the reliability of the reported outcomes and the overall quality of the evidence. For example, it is often difficult to achieve adequate blinding with physical treatments that produce cutaneous sensation. However, all guidelines developers face these same issues with regard to methodological considerations. Of additional note, heterogeneity with respect to interventions, treatment schedules, study populations, outcome measures, and comparators was frequently encountered, which reduced the comparability of individual trials. As a result, quantitative pooling of data through meta-analysis was not appropriate in most cases. Equally, the findings were sometimes inconsistent from one study or outcome measure to the next. Weighing the evidence in such situations inevitably involves value judgments and is subject to interpretation. Due to the absence of a clear consensus with regard to the relative importance of specific, validated outcome measures, individual study findings were not weighted according to the type of outcome assessed or measurement scale used.

The Ottawa Panel also faced other limitations with regard to the development of these guidelines. Articles in the scientific literature were only considered if they were written in English or French due to the additional time and resources required for translation. Moreover, the categorization of studies according to the type of intervention examined was not always straightforward, because in some cases a particular study could be applied to several categories. A decision was made as to which category of intervention a particular study best belonged in order to avoid duplication. This decision was inherently subjective and could contribute to potential variation in the Ottawa Panel's recommendations with other published clinical practice guidelines.

With regard to the calculation of treatment benefit, the Ottawa Panel considered a 15% improvement relative to control as clinically important. However, this criterion remains somewhat arbitrary and may not be applicable to all rehabilitation interventions or outcome measures. Interventions that showed clinically important benefits without statistical significance for validated outcomes (grade C+) were interpreted as worthy of consideration in the rehabilitation of stroke patients and were given positive recommendations. Most of the existing

EBCPGs on stroke rehabilitation did not consider clinical significance in synthesizing the evidence, which may further account for any differences in recommendations made by other guideline development groups. In the calculations of clinical relevance, difficulties also arose when the variance of data was not directly provided in the published articles. As a result, the Ottawa Methods Group, working closely with a senior biostatistician, developed a standardized methodology to estimate the variance of data (Appendix 2 in the original guideline document). This was the best conservative approximation that could be used to produce the Ottawa Panel recommendations.

Finally, the Ottawa Panel did not formally assess the cost-effectiveness of the various interventions studied. It is recognized, however, that cost and resource availability are important factors in the individual clinician's decision-making process.

The recommendations of the Ottawa Panel cannot replace clinical judgment, which is critical for applying the available evidence appropriately to the care of individual patients under specific circumstances.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Brosseau L, Wells GA, Finestone HM, Egan M, Dubouloz CJ, Graham I, Casimiro L, Robinson VA, Bilodeau M, McGowan J. Clinical practice guidelines for transcutaneous electrical nerve stimulation (TENS). *Top Stroke Rehabil* 2006 Spring;13(2):61-3.

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

**DATE RELEASED**

2006

**GUIDELINE DEVELOPER(S)**

Ottawa Panel - Independent Expert Panel

**SOURCE(S) OF FUNDING**

Ottawa Panel

**GUIDELINE COMMITTEE**

Ottawa Panel Evidence-Based Clinical Practice Guidelines Development Group

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**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available for purchase from the [Thomas Land Publishers, Inc. Web site](#).

Print copies: Available from Thomas Land Publishers, Inc., Subscription Office, P.O. Box 361, Birmingham, AL 35201-0361; Email: [TLPsubs@ebSCO.com](mailto:TLPsubs@ebSCO.com)

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on December 12, 2006. The information was verified by the guideline developer on January 19, 2007.

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