Complete Summary

GUIDELINE TITLE

Ottawa Panel evidence-based clinical practice guidelines for electrotherapy and thermotherapy interventions in the management of rheumatoid arthritis in adults.

BIBLIOGRAPHIC SOURCE(S)

Ottawa Panel evidence-based clinical practice guidelines for electrotherapy and thermotherapy interventions in the management of rheumatoid arthritis in adults. Phys Ther 2004 Nov;84(11):1016-43. [118 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Rheumatoid arthritis

GUIDELINE CATEGORY

Management
Rehabilitation
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Orthopedic Surgery
Physical Medicine and Rehabilitation
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Occupational Therapists
Physical Therapists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To promote appropriate use of electrotherapy and thermotherapy in the management of rheumatoid arthritis (RA)

TARGET POPULATION

Adult patients (18 years of age) with a diagnosis of rheumatoid arthritis (RA) according to the 1987 American Rheumatism Association (ARA) criteria.

A patient was said to have RA if he or she satisfied at least 4 of the following 7 ARA criteria:

- Morning stiffness
- Arthritis of 3 or more joints
- Arthritis of the hand joints
- Symmetric arthritis
- Rheumatoid nodules
- Serum rheumatoid factor
- Radiologic changes

INTERVENTIONS AND PRACTICES CONSIDERED

Electrotherapy and Thermotherapy

1. Low-level laser therapy (LLLT)
2. Therapeutic ultrasound
    - Pulsed
    - Continuous
3. Thermotherapy
    - Paraffin baths
    - Cryotherapy
4. Transcutaneous electrical nerve stimulation (TENS)
    - High frequency
    - Low frequency
    - Acupuncture-like

Interventions Considered But Not Recommended

- Electrical stimulation of muscle
- Exercise

MAJOR OUTCOMES CONSIDERED

Organ Systems and Impairment

- Number of inflamed joints
- Number of acute phase reactants (e.g., erythrocyte sedimentation rate)
- Radiological damage
- Side effects

Abilities and Disabilities

- Pain reduction
- Muscle force
- Range of motion (ROM)
- Postural status
- Duration of morning stiffness

Life Habits and Handicap Situation

- Global physician assessment
- Global patient assessment
- Gait status
- Walking speed
- Walking distance
- Cadence
- Stride length
- Functional status
- Patient adherence
- Patient satisfaction
- Length of stay
- Discharge disposition
- Quality of life
- Return to work

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The library scientist developed a structured literature search based on the sensitive search strategy for randomized controlled trials (RCTs)-a strategy

recommended by The Cochrane Collaboration with modifications to that strategy. The Cochrane Collaboration method minimizes bias through a systematic 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, there was no control over the outcomes the authors decided to measure.

The library scientist expanded the search strategy to identify case-control, cohort, and nonrandomized 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 2002. Also searched were 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 Evidence-Based Clinical Practice Guidelines (EBCPGs) Web site. Finally, reference lists of all of the included trials were searched for relevant studies and content experts were contacted for additional studies.

In the first round of study inclusion or exclusion, 2 independent reviewers, trained and experienced occupational therapist or physical therapist students, appraised the titles and abstracts of the literature search using a checklist with the a priori–defined selection criteria. More junior students were paired with fourth-year occupational therapist or physical therapist students who were experienced with the Philadelphia Panel methodology. Each pair of reviewers was assigned to a specific intervention. Within each pair of reviewers, individuals independently read the title and abstract of each article and created an individual list of all of the articles of the database with a reason for 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 who is a methodologist and a clinical expert in arthritis checked the 2 independent lists of articles and the reason for inclusion or exclusion to determine potential inconsistencies. Eleven percent of the abstracts reviewed needed the consultation of the senior reviewer. For the second round of inclusion and exclusion, 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.

Study Inclusion/Exclusion Criteria

The inclusion/exclusion criteria were based on previous criteria used by the Philadelphia Panel. This list of criteria, which had been created for multiple diagnoses, including back and neck pain, was adapted and approved by the Ottawa Methods Group (OMG) for use with rheumatoid arthritis (RA).

All original comparative controlled studies that evaluated the specific intervention in a sample of patients with RA were included: RCTs, controlled clinical trials (CCTs), cohort studies, and case-control studies. (Controlled clinical trials are the same as RCTs except that, according to the Jadad scale, CCTs are either not randomized or poorly randomized.) Crossover studies were included, and, to avoid potential confounders, the data from only the first part of the study (before crossing) were analyzed. (Data from the first part are more specific than data

from the second part because once the study patients change from the intervention group to the placebo group, the outcome could be due to either the intervention or the placebo. Thus, such results are not useful for measuring the special effect of each intervention.)

Uncontrolled cohort studies (studies with no comparison group) and case series were excluded, as were eligible studies with greater than 20% dropout rates or a sample size of less than 5 patients per group. Abstracts were excluded because none of the abstracts found had sufficient data for analysis and the full studies of the abstracts could not be obtained from the authors. Trials published in languages other than French and English were not analyzed because of the time and cost involved in translation. Head-to-head studies (that is, the comparison of 2 active interventions, such as therapeutic exercises versus transcutaneous electrical nerve stimulation) were generally excluded in these recommendations.

NUMBER OF SOURCE DOCUMENTS

For low-level laser therapy (LLLT), 11 articles were initially considered relevant and 5 randomized controlled trials (RCTs) involving 204 patients with rheumatoid arthritis were ultimately included.

For therapeutic ultrasound, 8 studies were initially included and 1 RCT involving 50 patients was ultimately included.

For thermotherapy, 23 trials were initially included and 2 RCTs involving 76 patients were ultimately included.

For transcutaneous electrical nerve stimulation (TENS), 9 articles were initially included and 3 RCTs involving 78 patients were ultimately included.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

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

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The methodological quality of the trials was assessed 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.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction

Using predetermined extraction forms, the pairs of reviewers independently extracted data from included articles on the population characteristics, details of the interventions, trial design, allocation concealment, and outcomes. The pairs of reviewers assessed methodological quality 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.

Statistical Analysis

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 2 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."

Heterogeneity (i.e., variability or difference between studies) was tested using the chi-square statistic. Data heterogeneity was tested among the results of different included studies to make sure that only homogeneous data were pooled together. When heterogeneity was not significant, fixed-effect models were used. A fixed-effect model is a statistical model that stipulates that the units under analysis (e.g., participants in a meta-analysis study) are the ones of interest and thus constitute the entire population of units. Fixed-effect models were used to generalize data across the included studies.

Random effects models include both within-study sampling error (variance) and between-studies variation in the assessment of the uncertainty (confidence interval) of a meta-analysis' results and are more severe than fixed effect models. Such random-effects models were used when heterogeneity was significant. All figures were created using Cochrane Collaboration methodology (www.cochrane.org).

Based on previous studies in the musculoskeletal domain and on consensus, clinical improvement for all interventions studied by the Ottawa Panel was defined as 15% improvement relative to a control. This figure can be justified because it was developed by the Philadelphia Panel, whose members are experts in musculoskeletal practice, and confirmed by another panel (the Ottawa Panel) whose members included specialists in rheumatology and an expert biostatistician.

To determine clinical improvement, the absolute benefit and relative difference in the change from baseline were calculated. Absolute benefit was calculated as the improvement in the treatment group less the improvement in the control group, maintaining the original units of measurement. Relative difference was calculated

as the absolute benefit divided by the baseline mean (weighted for the intervention and control groups). For dichotomous data, the relative percentage of improvement was calculated as the difference in the percentage of improvement between the intervention and control groups.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The development process of these evidence-based practice guidelines (EBCPGs) was similar to that of the Philadelphia Panel, except that a different target population was used. Briefly, the Ottawa Methods Group (OMG), a group of 9 methodologists with experience in developing EBCPGs, asked professional associations interested in the care of people with rheumatoid arthritis (RA) for suggestions of individuals with both clinical expertise in the management of the disease and familiarity with EBCPGs. From among the suggestions given, the OMG chose 9 experts to serve as panel members. These experts in RA were a rheumatologist, a physiatrist, a physician with experience in evidence-based medicine, a family physician, 3 physical therapists (including one who practiced acupuncture and one involved in clinical research), an occupational therapist, and a patient with RA. The Ottawa Panel consisted of these 9 experts and all members of the OMG.

One OMG member assembled a research and support staff with expertise in meta-analyses, rheumatology rehabilitation interventions, research methods, or the development and assessment of EBCPGs. The OMG then established a priori a set of inclusion criteria for the study designs, subject samples, interventions, and outcomes to allow the research staff to select the most relevant material as evidence of the effectiveness of therapeutic exercise and manual therapy. The OMG also reviewed the inclusion criteria to ensure that the approach to the study selection was reproducible and systematic. This a priori protocol guided separate systematic reviews of the literature for each intervention. The research staff reviewed articles and created evidence tables for them, which the 9 clinical experts received in preparation for their meeting with the OMG. These tables were used as the basis for making the recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded by their level (I for randomized controlled trials [RCTs], II for nonrandomized studies) and strength (A, B, C+, C, or D) of evidence.

Grade A: Evidence from one or more 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: 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 RCTs of a statistically significant benefit favoring the control group (<0%: favors controls)

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were sent to the external experts for review. To judge clinical usefulness, the positive recommendations also were sent to 5 practitioners for feedback. Practitioners were selected from clinical settings in the Ottawa and Toronto regions and were a physical therapist, an occupational therapist, a physiatrist, a family physician, and a rheumatologist, all of whom were currently working with patients with rheumatoid arthritis (RA). Practitioners were asked 4 questions for each guideline: whether the recommendation was clear, whether the practitioners agreed with the recommendation, whether they felt that the literature search on therapeutic exercises and intensity 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.

The development of the draft Evidence-Based Clinical Practice Guidelines (EBCPGs) prepared for the expert members was in concordance with Appraisal of Guidelines Research and Evaluation (AGREE) criteria. Using AGREE (www.agreecollaboration.org), 2 trained physical therapists assessed the Ottawa Panel EBCPGs for rheumatoid arthritis (RA). This tool consists of 6 dimensions measured on a 4-point scale, where 1 represents "strongly agree" and 4 represents "strongly disagree." The dimensions are: (1) purpose, defined as overall objectives that described the potential impact of a guideline on society and populations of patients; (2) stakeholder involvement, defined as the extent to which the guideline represents the views of its targeted users; (3) rigor of development, which deals with the process used to gather and synthesize the evidence and with the methods to formulate the recommendations and to update them; (4) clarity and presentation, which refers to the language and format of the guideline; (5) applicability, which relates to the likely organizational, behavioral, and cost implications of applying the guideline; and (6) editorial independence, which refers to the independence of the recommendations and acknowledgment of possible conflict of interest from the guideline development group.

The Ottawa Panel's evidence-based practice guidelines on electrotherapy and thermotherapy for the management of rheumatoid arthritis are generally in accordance with other evidence-based practice guidelines, including those from the American College of Rheumatology, the American Pain Society, and the American Occupational Therapy Association.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is followed by recommendation grades (Level I or II and A, B, C+, C and D). Definitions of the recommendation grades are presented at the end of the "Major Recommendations" field.

Low-level Laser Therapy (LLLT)

LLLT applied to the foot, knee, or hand versus a placebo, level I (randomized controlled trial [RCT]): Grade A for pain at 3 months (clinically important benefit); grade C for function, tender joints, muscle force, and range of motion (ROM) at 3 and 6 months (no benefit). Patients with chronic rheumatoid arthritis (RA).

Therapeutic Ultrasound

Therapeutic ultrasound performed on the hand in water versus a placebo, level I (RCT): Grade A for tender joints at 10 weeks (clinically important benefit); grade C for swollen joints and morning stiffness at 10 weeks (no benefit). Patients with RA involving the hand (functional class I or II, chronic stage).

Thermotherapy

Cryotherapy applied to the knee joint versus a control, level I (RCT): Grade C for thermographic index (measurement [in degrees Celsius] obtained using infrared thermography of the joint) at 5 days (no benefit). Patients with chronic RA, and with obvious effusion of joints.

Wax applied to the hand and wrist versus a control, level I (RCT): Grade C for pain, ROM, muscle force, and function at 1 month (no benefit). Patients with functional class I or II with hands affected.

Wax applied to the hand or wrist and hand exercises versus a control, level I (RCT): Grade A for ROM at 1 month (clinically important benefit), grade C+ for pain and stiffness at 1 month (clinical benefit), grade C for muscle force and function at 1 month (no benefit). Patients with functional class I or II with hands affected.

Transcutaneous Electrical Nerve Stimulation (TENS)

Low-frequency TENS applied to the hand and wrist versus no stimulation, level I (RCT): Grade A for pain at 3 weeks (clinically important benefit), grade C+ for

power at 3 weeks (clinical benefit), grade C for work at 3 weeks (no benefit). Patients with chronic RA.

High-frequency TENS applied to the hand and wrist versus placebo, level I (RCT): Grade C for pain and joint tenderness, same day (no benefit). Patients with chronic RA.

High- versus low-frequency TENS applied to the hand and wrist, level I (RCT): Grade C for global patient (patient's assessment of overall disease activity or improvement) (Ottawa Panel, 2004) at 2 weeks (clinical benefit). Patients with chronic RA.

Definitions:

The recommendations were graded by their level (I for RCTs, II for nonrandomized studies) and strength (A, B, C+, C, or D) of evidence.

Grade A: Evidence from one or more 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 CCTs

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

Grade C: 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 RCTs of a statistically significant benefit favoring the control group (<0%: favors controls.)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for each recommendation (see "Major Recommendations")

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of electrotherapy and thermotherapy for the treatment and rehabilitation of adults with rheumatoid arthritis

POTENTIAL HARMS

None stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The Evidence-Based Clinical Practice Guidelines (EBCPGs) developed by the Ottawa Panel have some potential limitations due to methodological weaknesses. Although the included trials were selected based on well-established inclusion and exclusion criteria, selection was performed by occupational therapist and physical therapist students. Potential omission of studies due to reviewer inexperience could have led to selection bias. Consultation with a third reviewer and the use of the panel of senior clinical experts may have compensated in part for this potential methodological flaw. The EBCPGs also are limited by the inclusion and exclusion criteria for the included studies. For example, some reports of randomized controlled trials (RCTs) did not specify if the study sample included individuals in acute or chronic stages of rheumatoid arthritis (RA). Additionally, some studies lacked details about the specific characteristics of the exercise intervention such as intensity. This lack of specificity could be problematic for future clinical implementation of the guidelines, especially for the whole-body functional strengthening recommendation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Ottawa Panel is planning to implement these guidelines in the Arthritis Rehabilitation and Education Program of The Arthritis Society of Ontario.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Ottawa Panel evidence-based clinical practice guidelines for electrotherapy and thermotherapy interventions in the management of rheumatoid arthritis in adults. Phys Ther 2004 Nov;84(11):1016-43. [118 references] PubMed

ADAPTATION

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

DATE RELEASED

2004 Nov

GUIDELINE DEVELOPER(S)

Ottawa Panel - Independent Expert Panel

SOURCE(S) OF FUNDING

This study was financially supported by an unrestricted educational grant from the Cigna Foundation, Philadelphia, PA USA.

GUIDELINE COMMITTEE

Ottawa Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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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: None available

Print copies: Available from Lucie Brosseau, PhD, Physiotherapy Program, School of Rehabilitation Sciences, Faculty of Health Sciences, 451 Smyth Rd, University of Ottawa, Ottawa, Ontario, Canada K1H 8M5 (E-mail: LucieBrosseau@uottawa.ca).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 10, 2005. The information was verified by the guideline developer on April 9, 2005.

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