Complete Summary

GUIDELINE TITLE

Evidence-based clinical practice guidelines for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients.

BIBLIOGRAPHIC SOURCE(S)

Sanders SH, Harden RN, Vicente PJ. Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients. Chattanooga (TN): Siskin Hospital for Physical Rehabilitation; 2005. 41 p. [116 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Sanders SH, Harden N, Benson SE, Vicente PJ. Clinical practice guidelines for chronic non-malignant pain syndrome patients II: an evidence-based approach. J Back Musculoskeletal Rehabil 1999 Jan 1;13:47-58.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic non-malignant pain syndrome

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology
Physical Medicine and Rehabilitation
Psychiatry
Psychology
Rheumatology

INTENDED USERS

Health Care Providers
Health Plans
Hospitals
Occupational Therapists
Physical Therapists
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To provide a second evidence-based update to treatment guidelines for chronic non-malignant pain syndrome patients that were first published in 1995 and revised in 1999
- To incorporate new evidence with established research findings as it applies to an interdisciplinary rehabilitation approach

TARGET POPULATION

Patients with chronic non-malignant pain syndrome as defined in the original guideline document

Note: The guidelines do not apply to cancer, acute, or subacute pain patients, or routinely to those patients experiencing chronic pain who do not meet the criteria for chronic non-malignant pain syndrome.

INTERVENTIONS AND PRACTICES CONSIDERED

Clinical Evaluation

1. Physician evaluation to include detailed medical history, review of medical records and diagnostic data, and thorough physical examination (additional consultation with specialist if needed)
2. Psychological/behavioral evaluation to include mental status examination, functional behavioral analysis, developmental history evaluation, psychological/behavioral diagnostic testing
3. Physical function evaluation, including neurological, musculoskeletal, and activities of daily living assessments

Management/Treatment

Primary Treatment Modalities

1. Medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and antidepressants (primarily tricyclic compounds) and/or anticonvulsants (for neuropathic-based pain); ergotamine, antiemetics, serotonin receptor agonists, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, calcium channel blockers, and anticonvulsants (for headache pain); opioids and sedative-hypnotics (with discretion to avoid chronic use)
2. Separate treatment for alcohol or substance dependency, as needed
3. Physical therapy, focusing on active therapy with secondary time-limited, passive physical therapy (e.g., transcutaneous electronic nerve stimulation [TENS], ultrasound, heat/ice, and traction) if needed
4. Occupational therapy
5. Behavioral/psychological therapy, including pharmacological treatment for depression and anxiety, stress management training, relaxation training, cognitive behavioral therapy, operant therapy, and biofeedback
6. Vocational rehabilitation and disability management

Adjunctive Treatment Modalities

1. Trigger point injections, including muscle injection with botulinum toxin (Botox) (considered but not recommended for routine use)
2. Prolotherapy (considered but not recommended for routine use)
3. Nerve blockade procedures, such as sympathetic and/or epidural steroid injections (considered but not recommended for routine use)
4. Acupuncture (considered but not recommended)

More Invasive Medical Procedures (Note: The following are considered but not recommended)

1. Implantable infusion pumps
2. Implantable spinal stimulators
3. Radiofrequency denervation
4. Intradiscal electrothermal therapy (IDET)
5. Spine surgery

Continuation of Treatment and Follow-Up

1. Application of an upper limit of 20 total primary treatment days for chronic non-malignant pain syndrome (CPS) patients in most cases (upper limit may be extended based on documented program outcome and goals)
2. Application of a minimum of three months of follow-up with patients after completion of primary treatment
3. Provision of 6-12 months of follow-up when possible

MAJOR OUTCOMES CONSIDERED

- Patient's physical and general functional status
- Patient's ability to self-manage pain and related problems
- Patient's vocational/disability status
- Patient's use of opiate and sedative-hypnotic medications
- Patient's healthcare utilization for CPS (e.g., number of invasive medical procedures)
- Patient's level of subjective pain intensity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The research review process included Medline, Psych Scan, MedWeb, Cochrane Collaboration Reviews, and other practice guidelines published since September 1999 and major textbooks on assessment and treatment of chronic pain patients.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

As with the 1999 revision, the definition of adequate "evidence" was set high to insure that the current recommendations had substantial, empirical support. For this article uncontrolled, non-randomized and non-prospective studies were not considered adequate evidence to support or reject a given recommendation. Specifically, as in prior versions, adequate evidence was defined as "...the presence of at least two well-designed prospective, controlled outcome studies demonstrating effectiveness with at least 200 chronic pain patients, including chronic non-malignant pain syndrome patients. For a given study to be considered, it had to demonstrate at least a prospective, control research design using quantifiable, objective outcome measures, including function." Prospective, randomized, controlled trials were given the highest weight. Likewise, adequate evidence was assumed from one or more quality meta-analyses demonstrating effectiveness, or an objective, criterion based systematic review of existing literature, which included the minimum number of prospective controlled outcome studies, as noted above.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

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

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Treatment Goals

The treatment goals, as relevant for each case should include:

a. Improvement of physical function (e.g., increase range of motion, standing, walking).
b. Improvement of general functional status (e.g., increase activities of daily living (ADLs), social - recreational activities, home - domestic activities).
c. Increase in self-management of the chronic non-malignant pain syndrome (CPS).
d. Improvement of vocational/disability status (e.g., return to work, start job retraining, start classes to increase work options).
e. Reduction/discontinuation of opiate and sedative-hypnotic medications.
f. Reduction of healthcare utilization for the CPS (e.g., reduce medical procedures, inpatient admissions, outpatient office visits).
g. Reduction of pain level (e.g., reduce visual analogue scale scores, verbal rating scores, verbal descriptor scores)

The current guidelines continue to emphasize increasing patients' level of function and ability to self-manage their pain and related problems. While reduction of pain level is a goal, the other goals should be actively pursued even if no reduction in pain level occurs.

Clinical Evaluation

The current guidelines recommend that CPS patients be evaluated by healthcare professionals with specialized training in chronic pain management. The initial evaluation should be performed by a qualified physician and psychologist. The content of these medical and psychological evaluations needs to include a detailed medical and psychological/behavioral history, review of all clinical records and diagnostic data, and thorough physical and behavioral psychological examinations by the appropriate professionals. Patients' working diagnoses, appropriateness for treatment, basic treatment plan, and initial goals should be set by the initial evaluation team, with input and agreement obtained from the patient before treatment begins.

For those patients that are accepted and agree to treatment, a physical function evaluation should be completed. This should include neurological, musculoskeletal, and activities of daily living functional assessments by physical and/or occupational therapists trained in these evaluations and pain rehabilitation. If CPS patients have a work related injury, a realistic goal of returning to work, or pending disability issues, an evaluation of their occupational and functional capacities should be done at the end of initial treatment.

It is recommended that the clinical treatment team meet regularly to discuss patients' response to and progress in the rehabilitation program. Likewise, ongoing treatment revisions should occur as needed to reach as many of the treatment goals as possible.

Treatment

The evidence continues to accumulate that the most effective treatment for CPS patients is found within an integrated interdisciplinary pain rehabilitation program. Services need to be provided by a coherent team of healthcare professionals with specialized training in pain rehabilitation and management, with patients receiving coordinated care across disciplines.

CPS patients should be accepted for treatment if there is indication that significant improvement in at least four treatment goals is achievable. For those patients where responsiveness is not clear, it is recommended that they be given a two to five day treatment trial, with assessment regarding initial responsiveness, compliance, motivation, and any kinds of initial treatment gains. If the initial response is promising, the remainder of the treatment plan can be implemented.

Primary Treatment Modalities

This section reviews and makes recommendations about various treatment modalities that have demonstrated evidence, as defined herein, of effectiveness either alone or in combination within an integrated interdisciplinary treatment approach. Likewise, some common and emerging modalities and technologies with insufficient evidence are reviewed. When recommended, a treatment should be available to CPS patients within an integrated pain rehabilitation program as their clinical condition warrants.

Medication Management

The research literature continues to provide increasing evidence that antidepressant medications can be beneficial for symptomatic treatment of CPS patients. Also, evidence continues to grow demonstrating that the tricyclic antidepressants and certain anticonvulsant medications can significantly reduce the subjective pain experience in neuropathic based pain. Thus, these medications are recommended for application to CPS patients, as their clinical condition would indicate. Evidence also continues to accumulate supporting certain medications with CPS patients suffering from primary migraine headache. There are useful and appropriate listings and guidelines for application of various medications for migraine headache. The evidence supports the systematic palliative or prophylactic use of non-steroidal anti-inflammatory, ergotamine, anti-emetic, serotonin receptor agonist, tricyclic antidepressant, angiotensin-converting enzyme (ACE)-inhibitor, beta-adrenergic blocker, calcium channel blocker, and anticonvulsant medications. It is recommended that when indicated these medications, as delineated in the referenced guidelines, be applied to CPS patients suffering from migraines.

Researchers are beginning to look at chronic application of oral and transdermal opioids using better controlled research designs; however, thus far, they lack the specified scientific rigor as persuasive evidence. At this time there are no randomized controlled, long-term trials or other appropriate experimental evidence demonstrating improvement in function or other objective measures associated with opioid usage in non-cancer CPS populations. In addition, without considering issues of addiction or dependency, some studies have found a significant increase in "problem drug behavior" with regular usage (e.g., dose violations, lost prescriptions, multi-sourcing). Given the continued lack of quality research and the growing concerns about the increasing frequency and abuse of

opioid prescriptions, the current guidelines still do not recommend the use of opioid medications with CPS patients. Since the 1999 revision, there has also been no substantial evidence supporting the routine use of sedative-hypnotic medications with these patients either. Thus, this drug classification is also not recommended.

If opioids or sedative-hypnotics are used, it should be on a very time limited basis (10-15 days). If other published guidelines are employed for long-term use of opioid or sedative-hypnotic medication, there should be clear evidence that the patient is not demonstrating significant impairment, such medication application produces a clinically meaningful increase in function, and the benefits and any clinical problems are frequently reassessed.

The current guidelines continue to recommend that patients demonstrating primary alcohol or other substance abuse dependency on nonprescribed substances should be treated separately for these issues.

Physical and Occupational Therapy

The scientific literature continues to accumulate and support, at least for CPS low back pain patients, the need to receive active physical and/or occupational therapy. The focus of physical and occupational therapies should be on helping patients learn awareness of body mechanics and dynamic posture, initiation and activation of a long-term exercise program to gradually increase general fitness, strength, coordination, and a range of flexibility and motion, postural and muscle balance, as well as specific physical coping strategies. Passive treatment methods should be only used in a secondary supportive role. Activity and/or job specific occupational therapy interventions should be used when appropriate, along with therapeutic recreation and sleep hygiene for those patients showing impairments in these areas.

Behavioral/Psychological Therapies

The research literature continues to provide a strong evidence basis for the importance and need for behavioral/psychological treatment. If significant depression or anxiety is present, psychological/behavioral treatment is recommended, as well as appropriate pharmacological interventions for these symptoms. CPS patients should receive and have access to stress management training, relaxation training, cognitive behavioral therapy, operant therapy, and biofeedback as their condition warrants.

Vocational Rehabilitation and Disability Management

Dealing with vocational and disability issues remains important for many CPS patients. Recommendations are for a focus on optimizing function, including return to work when possible. Job site analysis, job specific reconditioning, and functional capacity assessments, should be pursued when appropriate.

Adjunctive Treatment Modalities

Trigger Point and Botox Injections, Prolotherapy, Nerve Blocks, and Acupuncture

There has been an increasing use of trigger point and botox injections, prolotherapy, nerve blocks, and acupuncture for CPS patients over the last five years. This is in spite of a lack of any convincing quality evidence that any of these techniques work for this patient population. Thus, as with earlier guidelines, these methods are not recommended for use with CPS patients.

More Invasive Medical Procedures

Implantable Infusion Pumps and Spine Stimulation Devices

Studies and systematic reviews regarding the efficacy of infusion pumps and spinal cord stimulators have increased. Given the continued absence of quality research, however, the current guidelines do not recommend using implantable infusion pumps or spinal cord stimulators with CPS patients.

Radiofrequency Denervation, Intradiscal Electrothermal Therapy (IDET), and Spine Surgery

Application of radiofrequency denervation techniques and IDET for chronic back pain is also on the rise. While there are a number of uncontrolled and single group studies, the research literature to date is of poor quality and does not support usage with CPS patients. Thus, these techniques are not recommended.

There is increasing evidence that with certain back pain patients, spine surgery is indicated and can be quite effective. However, the evidence is still very weak regarding application to CPS patients. Therefore, the current guidelines recommend that spinal surgery be avoided with CPS patients with the following exceptions: presence of a new lesion, significant neurological deficit or progression, or clinically significant spine instability.

Treatment Intensity and Timing

The literature continues to support outpatient treatment for CPS patients whenever possible, with an upper limit of 20 total primary treatment days in most cases. Obviously, this upper limit may need to be extended based upon the specific documented outcomes and goals for a given treatment program. Consistent with effective treatment outcome studies, CPS patients should be followed for at least three months after the primary clinical care has been completed. If possible, 6 to 12 month follow-up is preferable, but sometimes not feasible. For chronic back pain patients in general, and CPS patients in particular, the research literature continues to support early intervention whenever possible.

CLINICAL ALGORITHM(S)

A clinical algorithm depicting a summary of the practice guidelines is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved medical care for chronic non-malignant pain syndrome patients, resulting in increased level of functioning and ability to self-manage pain and related problems

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Sanders SH, Harden RN, Vicente PJ. Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients. Chattanooga (TN): Siskin Hospital for Physical Rehabilitation; 2005. 41 p. [116 references]

ADAPTATION

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

DATE RELEASED

1995 (revised 2005)

GUIDELINE DEVELOPER(S)

Siskin Hospital for Physical Rehabilitation (Chattanooga, TN) - Hospital/Medical Center

SOURCE(S) OF FUNDING

Siskin Hospital for Physical Rehabilitation

GUIDELINE COMMITTEE

Not stated

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.

This guideline updates a previous version: Sanders SH, Harden N, Benson SE, Vicente PJ. Clinical practice guidelines for chronic non-malignant pain syndrome patients II: an evidence-based approach. J Back Musculoskeletal Rehabil 1999 Jan 1;13:47-58.

GUIDELINE AVAILABILITY

Electronic copies: None available.

Print copies: Requests can be sent to Steven H. Sanders, Ph.D., Siskin Hospital, One Siskin Plaza, Chattanooga, TN 37403. Email: ssanders@siskinrehab.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 9, 2001. The information was verified by the guideline developer as of November 26, 2001. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on September 15, 2005. The updated information was verified by the guideline developer on October 4, 2005.

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