Complete Summary

GUIDELINE TITLE

Clinical practice guidelines for chronic non-malignant pain syndrome patients II: An evidence-based approach.

BIBLIOGRAPHIC SOURCE(S)

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. [65 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Chronic non-malignant pain syndrome

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Physical Medicine and Rehabilitation

INTENDED USERS

Occupational Therapists
Physical Therapists
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based revisions to the practice guidelines for treating chronic non-malignant pain syndrome patients published in 1995 and adopted by the American Academy of Physical Medicine and Rehabilitation in 1996 (Sanders SH, Rucker KS, Anderson KO, et al. Clinical practice guidelines for chronic non-malignant pain syndrome patients. J Back Musculoskeletal Rehab 1995;5:115-20)

TARGET POPULATION

Patients with chronic non-malignant pain syndrome

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 active and passive range of motion, muscle strength and stamina assessment, and activities of daily living evaluation

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 agonists, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, calcium channel blockers, and anticonvulsants (for headache pain); opioids and sedative-hypnotics (with discretion)
2. Treatment for alcohol or substance dependency, as needed
3. Physical therapy, including active therapy and time-limited, passive physical therapy (e.g., transcutaneous electronic nerve stimulation [TENS], ultrasound, heat/ice, and traction)
4. Occupational therapy
5. Behavioral/psychological therapy, including pharmacological treatment for depression and anxiety, stress management training, relaxation training,

cognitive behavioral therapy, contingency management techniques, biofeedback, bibliotherapy for patient education, marital/family therapy
6. Vocational rehabilitation and disability management

Adjunctive Treatment Modalities

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

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

1. Ablative surgery
2. Implantable spinal stimulators
3. Continuous infusion devices
4. Brain stimulation

Continuation of Treatment and Follow-Up

MAJOR OUTCOMES CONSIDERED

- Degree of misuse, overuse, or dependency on medications
- Number of invasive medical procedures
- Patient´s level of function and physical activity
- Patient´s ability to self-manage pain and related problems
- Patient's ability of return to productive activity at home, socially and/or at work
- Level of subjective pain intensity
- Treatment costs relative to quality of care

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, and MedWeb searches of published articles from 1995 through September 1999. Major textbooks published during that time addressing the assessment and/or treatment of chronic pain were also reviewed for research citations and supportive evidence. Finally, practice guidelines published since the 1995 guidelines relating to chronic pain management were also reviewed for research citations.

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

For purposes of the current revision recommendations, adequate evidence basis for a given modality or recommendation 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, controlled research design using quantifiable, objective outcome measures, including function. Anecdotal case studies or repeated case series were not considered adequate evidence. Prospective, controlled, and randomized trials were given the highest priority. Adequate evidence was also assumed from one or more quality meta-analyses demonstrating effectiveness. In those areas not directly related to treatment interventions, such as patient selection and outcome goals, revisions were considered if they improved clarity or fair application.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Revisions to the 1995 guidelines focused on the presence or absence of supportive quality research. Unlike the original guidelines, review of common clinical practice across major pain treatment facilities was used to identify possible additional treatment modalities and modes of application, but it was not considered "evidence" to substantiate a given technique's inclusion in the guidelines for chronic non-malignant pain syndrome patients. For those modalities where reasonable evidence existed for inclusion in the 1995 guideline, a review for additional quality research was also done to increase or decrease the evidence for such a modality.

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

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Treatment goals

The current guidelines recommend retaining the treatment goals originally outlined in the 1995 guidelines. These include:

a. Reduce the misuse, overuse, or dependency on medications (defined here as continuous use of therapeutic levels of opioids or sedative/hypnotics, or any other medications for pain or related symptoms, above the maximum recommended daily doses or duration, and physical or psychological dependency), and reduce the use of invasive medical procedures
b. Maximize and maintain optimal physical activity and function
c. Return to productive activity at home, socially, and/or at work
d. Increase the patient´s ability to self-manage pain and related problems
e. Reduce subjective pain intensity
f. Reduce/eliminate the use of ongoing health care services for primary pain complaint
g. Provide useful information to the patient and professionals involved in the case to help resolve any medical/legal issues and allow case settlement
h. Minimize treatment cost without sacrificing quality of care

As the 1995 guidelines recommended, the emphasis should be on increasing the patient´s level of function and ability to self-manage pain and related problems. This should be the focus of treatment regardless of whether reduction in subjective pain intensity is feasible or there are medication dependency issues.

Given the increasing use of opioids, and to a lesser extent sedative-hypnotics, in clinical practice over the last five years, treatment goal (a) may be seen as controversial. As will become clear from the research literature presented herein, this increased usage with chronic pain patients is without any strong scientific merit. Likewise, by definition, the chronic non-malignant pain syndrome (CPS) patient may over invest in pharmacological or procedural solutions to his problem. This sets up an increasing risk for substance overuse, misuse, and physical or psychological dependency, as well as excessive procedural applications. Therefore, treatment goal (a) is an important one for the chronic non-malignant pain syndrome patient. Again, this may not be the case for chronic pain patients not meeting chronic non-malignant pain syndrome criteria.

The definition of medication misuse, overuse, or dependency also needs further clarification for accurate application. As defined, it would involve a patient using therapeutic levels of opioids or sedative-hypnotics on a longitudinal or continuous basis, or at levels that produce physical or psychological dependency as defined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV). In addition, if a patient were using other medications for pain-related symptoms above maximum recommended daily doses or duration (with or without opioids or sedative-hypnotic use), she would also be considered as misusing medications.

Clinical evaluation

No basic revisions are recommended from the 1995 guidelines regarding clinical evaluation. Specifically, the evaluation should be performed by health care professionals with adequate training in pain rehabilitation. It is recommended a physician and psychologist provide the initial clinical evaluation. The physician evaluation should include at least a detailed medical history, review of medical records and diagnostic data, and a thorough physical examination. At the physician´s discretion, there may need to be consultation with additional specialists based upon the initial evaluation. Specialists may include neurologists, neurosurgeons, orthopedic surgeons, psychiatrists, and any others that are clinically appropriate. The psychological/behavioral evaluation should include at least a clinical mental status examination, functional behavioral analysis, developmental history evaluation, and psychological/behavioral diagnostic testing necessary to clarify or quantify the patient´s symptom presentation. The evaluation team should meet and determine working diagnoses, patient´s appropriateness for treatment, basic treatment plan, and set initial goals (e.g., return to work, increase general function, reduce subjective pain intensity, etc.). These goals should be agreed upon by the treatment team and the patient before treatment begins.

If the patient is accepted for treatment, a physical function evaluation should be completed and include active and passive range of motion, muscle strength and stamina assessment, and an activities of daily living evaluation. For those patients with a realistic goal of returning to work or a pending disability claim, vocational and disability evaluations are recommended at the end of initial treatment, when possible. The reimbursement climate over the last five years has made it quite difficult to obtain a vocational evaluation in many cases. However, disability evaluations are still typically reimbursed. Hopefully, with time and the impact of ignoring vocational needs, there will be more of a positive long-term view of the cost-effectiveness of vocational assessments. For the disability evaluation part of the process, it is recommended that at least a residual functional capacity assessment and impairment rating be performed at treatment completion.

As the 1995 guidelines also recommended, the patient should be continuously monitored and evaluated for progress and problems throughout treatment, with ongoing updates in treatment planning to realize as many treatment goals as possible.

Treatment

For the most part, the 1995 guideline recommendations are incorporated in the current guidelines. As the research literature continues to clearly demonstrate, chronic non-malignant pain syndrome patients are best treated in an integrated interdisciplinary program. The program needs to maximize continuity of care by employing a coordinated group of health care professionals (i.e., physicians, psychologists, physical and occupational therapists, vocational evaluators, counselors, and specialty consultants) who evaluate and treat the patient as a team. Likewise, the focus of care should be on achieving relevant treatment goals, with regular ongoing interaction between the health care professionals, patient, and the patient´s family.

One revision is recommended to the 1995 guidelines regarding patient selection. While the original guidelines noted "those chronic non-malignant pain syndrome patients who exhibit a reasonable chance of showing significant improvement in at least three of the eight basic program goals" should be accepted for interdisciplinary treatment, the current guidelines recommend modifying these numbers. It is recommended that chronic non-malignant pain syndrome patients be accepted for treatment if there is a reasonable chance of showing significant improvement in at least three of the first seven program goals (i.e., increased productivity, reduced medication misuse, reduced subjective pain intensity, etc.), with the eighth goal (h) excluded from this acceptance criteria. The eighth goal is a program goal versus an individual patient goal; thus, it is inappropriate to apply it to acceptance criteria to chronic non-malignant pain syndrome patients.

In accordance with the 1995 guidelines, the current recommendations for patient selection continue to provide an opportunity for patients when it is not clear if treatment response will be positive. Unless these patients refuse do not accept treatment goals, or can not participate due to financial or other issues, it is recommended they have a trial acceptance and be monitored closely for the first two to five full treatment days. Their initial response, compliance, motivation, and understanding of goals can be assessed. If they demonstrate compliance and signs of any initial progress during this trial period, they can continue in the full interdisciplinary treatment with continued review to completion. For those patients showing poor compliance, motivation, understanding of goals, or no signs of progress during this initial trial period, feedback should be administered, and they should be given two to three additional treatment days to show more improvement and/or better compliance. Barring specific documented reasons otherwise, patients not demonstrating improvement within these two-three additional treatment days should be discharged from the program. Discharge documentation should include current clinical and functional status and reasons for early discharge.

Primary treatment modalities

As the original 1995 guidelines indicated, there are numerous outcome studies available demonstrating that interdisciplinary pain rehabilitation can effectively produce significant improvement in chronic non-malignant pain syndrome patients. Until recently, however, the specific treatment modalities necessary to achieve improvement were unclear. This is still the case to some extent, although, as will be documented in the following sections, there is a growing base of evidence regarding certain modalities to help guide recommendations about their inclusion. The subsequent sections will provide recommendations by modality, as

was done in the 1995 guidelines, with a focus on clarifying the empirical basis for these recommendations based upon existing research. As already noted, the current recommendations overlap many of those made in other treatment guidelines, with some notable exceptions. It is recommended that the following treatment modalities and procedures be available within a structured interdisciplinary program/center to chronic non-malignant pain syndrome patients as their clinical conditions warrant.

Medication management

There is consistent and growing evidence that nonsteroidal anti-inflammatory and antidepressant medications (primarily tricyclic compounds) can be beneficial to chronic non-malignant pain syndrome patients. The American Pain Society (APS) has published an updated document titled "Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain (Fourth Edition)" (Glenview [IL]: American Pain Society, 1999), which delineates in more detail the recommended application of nonsteroidal anti-inflammatory and antidepressant medications. Likewise, there is consistent and growing evidence that tricyclic antidepressants and certain anticonvulsants can significantly reduce the subjective pain experience in chronic non-malignant pain syndrome patients suffering specifically from neuropathic pain. Therefore, tricyclic antidepressant and/or anticonvulsant drugs are recommended for use with chronic non-malignant pain syndrome patients experiencing primarily neuropathic-based pain.

Since the 1995 guidelines, there has been major advancement in pharmacological management of chronic non-malignant pain syndrome patients with headache as the primary source of pain. Unfortunately, the Agency for Health Care Research and Quality (AHRQ) guideline project referenced in the 1995 guidelines never came to fruition or publication due to budget cuts. As a substitute for at least primary migraine headache chronic non-malignant pain syndrome patients, the pharmacological protocols disseminated by the American Medical Association (AMA) have a solid empirical basis and are recommended. This includes the systematic palliative or prophylactic use of nonsteroidal anti-inflammatory, ergotamine, antiemetic, serotonin agonist, tricyclic antidepressant, angiotensin-converting enzyme (ACE) inhibitor, beta-adrenergic blocker, calcium channel blocker, and anticonvulsant medications. The American Medical Association recommendations caution against the widespread use of opioid and sedative-hypnotic medicines with migraine headache patients, particularly for chronic daily headaches, due in part to medication rebound effects. Very limited, infrequent use of opioids and sedative-hypnotics with headache chronic non-malignant pain syndrome patients to deal with acute flare-ups may be appropriate and is common in practice, however, there is no consistent supporting evidence for such intervention.

For over 10 years there has been an active call for quality research in the use of opioid-based analgesics and sedative-hypnotic medications to treat chronic pain patients. Likewise, there has been increasing commercial and clinical pressure to routinely use these medications. In spite of all this, there are no good randomized, controlled trials of sufficient length to demonstrate long-term efficacy and safety of these two drug groups with chronic non-malignant pain syndrome patients. While several recent studies indicate some tentative positive effects on the subjective pain report, the evidence basis is simply not there to make a

blanket recommendation for routine use of these two drug groups. Thus, consistent with the 1995 guidelines, until well-controlled, randomized outcome studies of sufficient length indicate that opioids or sedative-hypnotic medications significantly improve treatment effectiveness for selected chronic non-malignant pain syndrome patients, these drugs need to be used with caution, and avoided if possible. It is recommended that if these two drug groups are used, they be used for a limited time (routinely from 1 to 10 days) for both headache and non-headache, chronic non-malignant pain syndrome patients to treat acute pain flare-ups. As the 1995 guidelines recommended, "If long-term opioid or sedative-hypnotic medications are considered with chronic non-malignant pain syndrome patients, they should be applied only when there is clear evidence that they do not impair the patient but produce significant and sustained improvement in function."

In accordance with the 1995 guidelines, it is also recommended that patients demonstrating primary alcohol or other substance abuse dependency be treated for this separately before attempting to actively participate in an interdisciplinary chronic pain program.

Physical and occupational therapy

No revisions are necessary to the 1995 guidelines regarding the use of physical and occupational therapy. Specifically, chronic non-malignant pain syndrome patients need to receive primarily active and, secondarily, time-limited, passive physical and occupational therapy. While the recent scientific literature suggested such interventions do not necessarily have any lasting effect past the point they are applied, research also has shown that implementing an active functional restoration component with chronic non-malignant pain syndrome patients is a necessary and important part of improving their general function. Thus, patients clearly need to have access to such interventions and be encouraged to continue self-application on a long-term basis. As the 1995 guidelines noted, the focus of such treatment should be ongoing "education to teach the patient awareness of body mechanics and dynamic posture as well as active exercise programs to gradually improve general fitness, strength, coordination, range and flexibility of motion, and posture. More passive treatment methods, such as transcutaneous electronic nerve stimulation (TENS), ultrasound, heat/ice, and traction, should only be used in a secondary supportive role to facilitate the patient´s ability to increase fitness, strength, and range and flexibility of motion.â These passive methods must be time-limited. Also, job-specific occupational therapy interventions should be available when needed along with therapeutic recreation and sleep ergonomics. The overall focus should be on establishing independently applied, home-based exercises and follow-up protocols the patient can continue to do after active treatment is finished.

Behavioral/psychological therapy

As with physical and occupational therapy, no major revisions are recommended to the 1995 guidelines regarding behavioral/psychological intervention for chronic non-malignant pain syndrome patients. There is a wealth of research support indicating that such interventions are effective with chronic non-malignant pain syndrome patients to make meaningful change in emotional, cognitive, behavioral, and physical issues associated with the chronic pain problem. Those

chronic non-malignant pain syndrome patients demonstrating significant depression and anxiety need behavioral/psychological and possibly pharmacological treatment for such symptoms. Any other co-morbid psychological/psychiatric conditions, such as, posttraumatic stress disorders, personality disorders, and social adjustment issues also need aggressive psychotherapeutic interventions. At the very least, behavioral/ psychological therapy needs to include stress management training, relaxation training, cognitive behavioral therapy, and contingency management techniques. Biofeedback interventions, especially for certain myofascial and vascular headache conditions, should be available, as well as bibliotherapy for patient education and limited marital and family therapy. As with the other treatment modalities, an individualized treatment plan should be developed for each patient and applied at the individual and/or group level in a coordinated fashion with the rest of care (for in- depth presentation and discussion of various psychological/behavioral methods for chronic non-malignant pain syndrome patients).

Vocational rehabilitation and disability management

As noted in the 1995 guidelines, addressing vocational and disability needs is an important part for many chronic non-malignant pain syndrome patients. This is not specifically an evidence-based recommendation; rather, it is a practical and obvious one to meet the important goal of optimizing function, including returning to work, where appropriate. While the whole area of disability management is still quite convoluted and confusing, those recommendations in the 1995 guidelines are still quite applicable. For those patients where return to work and/or disability are at issue, services such as job site analysis and job-specific reconditioning (work hardening), evaluation of ability to perform tasks (work capacity) and transferable skills, and residual functional capacity and impairment level assessments should be applied when possible. Although this is far from a definitive and absolute objective process, ignoring this area with chronic non-malignant pain syndrome patients typically creates more problems than it solves and does not foster complete rehabilitation. Obviously, the actual application of the various evaluative areas may well be out of the provider's control and/or not reimbursable. Thus, at the very least, obtaining a functional capacity assessment and impairment level rating is recommended.

Adjunctive treatment modalities

Nerve blocks and trigger point injections

The 1995 guidelines recommended limited use of nerve blockade and trigger point injections for certain patients to facilitate reduction in subjective pain intensity and participation in the rehabilitation process. This recommendation was based primarily on common practice and consensus among the original authors. A review of the research literature since the 1995 recommendations indicates revisions are in order. Specifically, a thorough review of the research literature failed to offer any evidence for the routine application of trigger point injections. While there are a number of uncontrolled case studies using trigger point injections in more acute pain presentations, there is virtually no consistent evidence for its application with chronic non-malignant pain syndrome patients to date. Thus, although it may be widely used in practice, evidence of its efficacy is lacking. Given this, the current guidelines do not recommend the use of trigger

point injections on a routine basis for chronic non-malignant pain syndrome patients until further evidence demonstrates the method produces significant effects.

In addition, since the 1995 guidelines, there has been an increasing clinical application of muscle injections of botulinum toxin (Botox). This technique evolved out of treatment for acute muscle spasticity and pain. As with trigger point injections, there are no randomized controlled trials demonstrating the use of this particular injection has any clinical utility with chronic non-malignant pain syndrome patients. In fact, a recent randomized, double-blind prospective study demonstrated Botox injections with patients showing symptoms consistent with chronic non-malignant pain syndrome had little, if any, clinical value over and above placebo or no treatment. Given this, the current guidelines also do not recommend the routine use of Botox injections with chronic non-malignant pain syndrome patients.

With regard to nerve blockade procedures (i.e., sympathetic and/or epidural steroid injections), the current research literature does not support their long-term effectiveness or routine usage with chronic non-malignant pain syndrome patients. Indeed, there is a lack of research applying these techniques to chronic non-malignant pain syndrome patients in any kind of randomized, controlled fashion. The conclusions drawn from the literature come primarily from application of these techniques to acute and subacute pain patients. For those patients, existing evidence suggests that the use of lumbar epidural steroid injections for low back pain is no more effective than placebo or no treatment regarding long-term improvement in function, pain, and mood. Given the lack of demonstrated efficacy for lumbar epidural steroid injections and no systematic, quality evidence regarding sympathetic nerve blockade, these techniques can not be recommended for routine use with chronic non-malignant pain syndrome patients at this time.

If a clinician does use these injections/nerve blockades with a chronic non-malignant pain syndrome patient, it is strongly recommended that the original limits set in the 1995 guidelines be applied. These recommended such interventions not be used in isolation, with an upper limit of 10 sets of trigger point injections or individual nerve blockade for a given patient unless significant improvement in function can be demonstrated as a result of additional interventions. Likewise, if the patient does not show a response after three sets of trigger point injections or individual nerve blockade, the procedure should be discontinued.

Acupuncture

Acupuncture was not included or recommended in the 1995 guidelines. The increased application of this technique for chronic pain patients and greater acceptance in mainstream Western medicine warrants offering recommendations in the current guidelines. Since the National Institutes of Health (NIH) consensus statement on acupuncture (Acupuncture. NIH Consensus State 1997) suggested it may have some value with certain pain syndromes, there has been increasing application in the clinical arena. Unfortunately, the National Institutes of Health statement was tenuous and based upon very limited evidence. Thus, the National Institutes of Health statement should not be viewed as adequate evidence for recommending acupuncture with chronic non-malignant pain syndrome patients.

In fact, a review of the literature since 1995 failed to show consistent, well-controlled research support for the routine application of acupuncture. Indeed, a recent study using more valid research methodology found that acupuncture was of little effectiveness for acute and chronic low back pain. Review of the patient sample used indicated that chronic non-malignant pain syndrome patients were included. Given this, and until more consistent, well-controlled studies demonstrate effectiveness, the current guidelines do not recommend that acupuncture be used with chronic non-malignant pain syndrome patients.

More invasive medical procedures

Since the 1995 guidelines, there have been no good, consistent research studies indicating ablative surgery should be considered for chronic non-malignant pain syndrome patients. Thus, it continues to be a recommendation that surgery be avoided. Exceptions to this, as stated in the 1995 guidelines, include "the presence of a new lesion; significant progressive neurological deficits, such as loss of bladder/bowel function or paralysis; or to correct clinically significant spine instability." Pain by itself does not justify a surgical approach.

The research literature since the 1995 guidelines regarding the use of implantable spinal stimulators, continuous infusion devices, and brain stimulation continues to provide inadequate evidence for application with chronic non-malignant pain syndrome patients. Thus, these methods are not recommended. This is particularly true, given the expense and level of invasiveness for the clinical benefit obtained (i.e., cost: benefit ratio).

The study by Burchiel and colleagues (Burchiel K, Anderson V, Brown F, et al. Prospective multi-center study of spinal cord stimulation for relief of chronic back pain and extremity pain. Spine 1996;23:2786-94) is of particular interest in making this recommendation for spinal cord stimulation. Of the available literature, this appears to be one of the better prospective clinical studies. (Though still suffering from a number of methodological limits.) It was prospective and used quasi-objective outcome measures. While the authors concluded that the findings supported the use of spinal cord stimulation with chronic non-malignant pain syndrome patients, a review of the findings lends serious doubt to this conclusion. Of the original 182 patients included in the study, at one-year follow-up the authors found 37 (21%) reported satisfaction and improvement in pain from using spinal cord stimulation. They failed to find any change in medication use or work/function. A 21% level of improvement is lower than one would expect with a placebo application. Unfortunately, since the study did not have a control group, the true value of such invasive intervention comes into question. While the authors noted that some of the patients in the original sample had not met the one-year, follow-up time frame, there was not enough specificity to factor out these patients. Also, the current literature search failed to find any follow-up studies incorporating these additional patients to get a clearer picture of the original sample responsiveness. Thus, the guideline developers were left with a study that does not provide strong support for spinal cord stimulation for chronic non-malignant pain syndrome patients. It exemplifies the weak research support for these invasive and expensive interventions.

Treatment intensity

In reviewing the outcome studies for interdisciplinary pain programs using the best treatment modalities recommended in the current guidelines, there is no evidence to support any changes in the 1995 guidelines for treatment intensity. Unless there are marked restrictions in mobility and ambulation, the presence of significant opioid or sedative-hypnotic prescription abuse and dependency, or major multiple organ system pathology and dysfunction, the chronic non-malignant pain syndrome patient should be treated on an outpatient basis. There should be a continuum of treatment intensity based upon the patient´s needs, which could range from contact once a week to daily, from one to eight hours per day, depending upon the clinical needs of the patient. Treatment intensity should be matched to clinical need to achieve as many treatment goals as possible. Regardless of the number of hours per day or days per week the patient is seen, research studies continue to show that effective outcome from such interdisciplinary treatment is accomplishable within a maximum of 20 treatment days. Thus, this 20-treatment-day upper limit for definitive intervention with chronic non-malignant pain syndrome patients is recommended. Obviously, there could be exceptions to this, and when that occurs, the extension of intervention and purpose should be clearly documented.

Although the evidence specifying the exact nature and need of follow-up with chronic non-malignant pain syndrome patients after active treatment has yet to be addressed in the research arena, from a practical management standpoint, the current guidelines continue to make those recommendations from the 1995 guidelines. Specifically, chronic non-malignant pain syndrome patients should be followed for at least three months after initial active treatment. It is recommended the patient be seen for a minimum of two follow-up treatment visits with the interdisciplinary team. More follow-up visits can be considered if there is true clinical need to enhance the patient´s ability to stabilize and continue to improve function over the course of time. Any such extension of follow-up needs to be documented, time limited, and monitored on a case-by-case basis. The primary goal of follow-up is to help the transition from active treatment to patient-controlled application of treatment protocols, leading to more independence. It is not to perpetuate dependency on the interdisciplinary treatment team, which would clearly be counterproductive for long-term improvement.

CLINICAL ALGORITHM(S)

None provided

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.

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 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. [65 references]

ADAPTATION

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

DATE RELEASED

1995 (updated 1999)

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

Authors: Steven H Sanders; Norman Harden; Suzanne E. Benson; and Peter J. Vicente

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is intended to provide evidence-based revisions to the practice guidelines for treating chronic non-malignant pain syndrome patients published in 1995 and adopted by the American Academy of Physical Medicine and Rehabilitation in 1996 (Sanders SH, Rucker KS, Anderson KO, et al. Clinical practice guidelines for chronic non-malignant pain syndrome patients. J Back Musculoskeletal Rehab 1995;5:115-20).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

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

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.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

For reprints or other information, please contact Steven H. Sanders, Ph.D., Siskin Hospital, One Siskin Plaza, Chattanooga, TN 37403; Telephone: (423) 634-1670; Fax: (423) 634-4570; E-mail: ssanders@siskinrehab.org.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/15/2004