Guideline Summary NGC-4342

Guideline Title
Guideline for the management of fibromyalgia syndrome pain in adults and children.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.

FDA Warning/Regulatory Alert
Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 25, 2010 – Ultram (tramadol hydrochloride) [X]: Ortho-McNeil-Janssen and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Warnings section of the prescribing information for tramadol, a centrally acting synthetic opioid analgesic indicated for the management of moderate to moderately severe chronic pain. The strengthened Warnings information emphasizes the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warns of the risk of overdosage.

Scope

Disease/Condition(s)
Fibromyalgia syndrome

Guideline Category
Diagnosis
Evaluation
Management
Treatment

Clinical Specialty
Family Practice
Internal Medicine
Neurology
Nursing
Pediatrics
Pharmacology
Physical Medicine and Rehabilitation
Psychiatry
Psychology
Rheumatology

Intended Users
Advanced Practice Nurses
Nurses
Pharmacists
Physical Therapists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)
- To provide evidence-based guidelines for diagnosis and management of fibromyalgia syndrome (FMS) in children and adults
- To improve the quality of care for children and adults

Target Population
Adults and children suffering from fibromyalgia syndrome

Interventions and Practices Considered

Diagnosis/Evaluation
1. Complete history and differential diagnosis
2. Pain assessment including pain intensity, pain affect, and pain location
3. Physical examination including general physical examination and tender point examination
4. Psychological and functional assessment
5. Laboratory assessment including complete blood count, erythrocyte sedimentation rate, muscle enzymes, liver function, and thyroid function tests

Management/Treatment of Fibromyalgia Syndrome in Adults
1. Pharmacologic therapies
   - Antidepressant medication, such as tricyclic antidepressants (e.g., amitriptyline or cyclobenzaprine); selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, alone or in combination with tricyclics)
   - Analgesics, such as non-steroidal anti-inflammatory drugs (NSAIDs) in combination with other medication (Note: NSAIDs are not recommended); tramadol, alone or in combination with acetaminophen; opioids
   - Sleep and anti-anxiety medications, such as trazodone, benzodiazepines, nonbenzodiazepine sedatives, L-dopa and carbidopa
   - Trigger point injections in patients with co-existent myofascial pain

   Note: Guideline developers considered but did not recommend anticonvulsant medication and hormone therapy including corticosteroids (unless there is concurrent joint, bursa, or tendon inflammation)

2. Nonpharmacologic therapies
   - Patient education about fibromyalgia syndrome and treatment options, pain management and self-management programs
   - Cognitive-behavioral therapy
   - Aerobic exercise
   - Clinician-assisted treatment, such as clinical hypnosis and biofeedback, acupuncture, chiropractic manipulations, therapeutic massage, and balneotherapy

   Note: Guideline developers considered but did not recommend dietary modifications, nutritional supplements, and biologic agents due to lack of sufficient research

3. Multidisciplinary treatment incorporating two or more strategies
4. Referral to a specialist

Evaluation/Management of Fibromyalgia Syndrome in Children and Adolescents
1. Assessment of pain including pain history, behavioral observations, physiologic and psychosocial cues, mood disorders, and functional status
2. Child and family education
3. Cognitive-behavioral therapy
4. Aerobic exercise and physical therapy
5. Sleep hygiene
6. Pharmacologic management (e.g., fluoxetine)
7. Family involvement and school integration

Major Outcomes Considered
Effect of treatment on pain relief, fatigue, sleep, function, self-efficacy, mood, and Fibromyalgia Syndrome Impact Questionnaire (FIQ) scores

Methodology

Methods Used to Collect/Select the Evidence
Hand-searches of Published Literature (Primary Sources)
Description of Methods Used to Collect/Select the Evidence

A comprehensive literature review was conducted to locate recently published systematic evidence reviews and to identify areas in which reviews were needed. This evidence was used in the development of the guideline.

Four sources of evidence review were used: (a) Cochrane Collaboration Reviews, (b) other published systematic reviews, (c) reviews commissioned by American Pain Society (APS), and (d) reviews conducted by APS panel and staff members. The Cochrane and other published reviews are listed in Table 1 of the original guideline document.

The reviews commissioned by APS were completed under the direction of Linda Tyler, PharmD (Utah Drug Information Service, University of Utah Health Sciences Center), and included use of opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, lidocaine, ketamine, tramadol, and miscellaneous medications used to treat fibromyalgia syndrome (FMS). The remaining 12 reviews were conducted by APS panel and staff members and are listed in Table 2 of the original guideline document. All reviews conducted by APS staff and by the Utah Drug Information Service used the same protocol for reviewing individual studies.

The databases, dates searched, and review methods used are described in each published evidence review. For reviews conducted by the Utah Drug Information Service and APS panel and staff members, the following databases and dates were included: MEDLINE (1966-April 2004), CINAHL (1982-April 2004), Embase (1988-April 2004), PubMed (1966-April 2004), HealthStar (1997-2000), Current Contents (2000-April 2004), Web of Science (1980-April 2004), PsycINFO (1887-April 2004), Science Citation Indexes (1996-April 2004), and the Cochrane Database (1993-2004). The abstracts were searched to identify research articles. Case reports, letters to the editor, articles describing diagnostic techniques, animal studies, and surveys reporting the incidence of pain were excluded. Published studies were reviewed and evaluated following a specific protocol.

Number of Source Documents

Not stated

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

The type of evidence for recommendations was ranked ordinarily in categories from I to V as follows:

I. Meta-analysis of multiple well-designed controlled studies
II. Well-designed experimental studies
III. Well-designed, quasi-experimental studies, such as nonrandomized controlled, single-group pre-post, cohort, time series, or matched-case controlled studies
IV. Well-designed nonexperimental studies, such as comparative and correlational descriptive and case studies
V. Case reports and clinical examples

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The evidence was classified by type and strength. The type of evidence for recommendations was ranked ordinarily in categories from I to V.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The fibromyalgia syndrome (FMS) guideline development process combined the review of available scientific evidence and the judgment of pain experts.

The interdisciplinary panel comprised 13 experts in various aspects of the management of pain associated with FMS. The panel and American Pain Society (APS) staff prepared multiple drafts of the document.

The panelists based recommendations labeled A or B primarily on the evidence. For recommendations labeled C or D, the panel used the available empirical evidence but based its recommendations primarily on expert judgment. The term panel consensus was used when the recommendation was a statement of panel opinion regarding desirable practice.

Rating Scheme for the Strength of the Recommendations

The evidence for the recommendations was summarized according to its strength and consistency. Strength of evidence ranged from A (the strongest evidence) to D (little or no evidence, or type V evidence only). The strength and consistency of the recommendations are as follows:
A. There is evidence of type I or consistent findings from multiple studies of types II, III, or IV.
B. There is evidence of types II, III, or IV, and findings are generally consistent.
C. There is evidence of types II, III, or IV, but findings are inconsistent.
D. There is little or no evidence, or there is type V evidence only.

Panel Consensus: Practice recommended based on the opinions of experts in pain management.

Cost Analysis
Published cost analyses were reviewed.

Method of Guideline Validation
Peer Review

Description of Method of Guideline Validation
Two drafts of the guideline underwent peer review, with 50 reviewers participating in the first review and 9 in the second; some reviewers read both drafts. Peer reviewers are listed in Appendix F of the original guideline document, except for those who chose to remain anonymous (two individuals). The questionnaire that reviewers used to evaluate the drafts was based on the Institute of Medicine’s Guidelines for Clinical Practice: From Development to Use.

Recommendations

Major Recommendations
These recommendations are presented in abbreviated form. Readers should refer to the text of the guideline document for a detailed discussion of each of the following topics.

Definitions for the type of evidence (I, II, III, IV, V) and the strength and consistency of evidence grades (A, B, C, D, Panel consensus) are provided at the end of the “Major Recommendations” field.

Fibromyalgia Syndrome Diagnosis and Assessment
1. Begin the evaluation of people with fibromyalgia syndrome (FMS) with a complete history and physical examination, focusing on illnesses that may mimic or complicate FMS, such as hypothyroidism or ankylosing spondylitis, or that can occur concurrently with FMS, such as tendinitis, systemic lupus erythematosus, rheumatoid arthritis, or osteoarthritis. The clinician should perform a complete joint examination, manual muscle strength testing, and neurologic examination. (Panel consensus)
2. Base the clinical diagnosis of FMS on the presence of widespread pain, defined as pain in all four body quadrants and axial pain, for at least 3 consecutive months. The only physical examination criterion for the diagnosis of FMS is the presence of excess tenderness to manual palpation of at least 11 of 18 muscle-tendon sites obtained through the manual tender point examination. (B)
3. Focus pain assessment on type and quality of pain, source, location, duration, time course, pain affect, and effects on quality of life. Use self-report as the primary source of pain assessment, and use the same pain measurement tool at subsequent visits. (B)
4. Evaluate the severity of other FMS symptoms, including fatigue, sleep disturbance, and mood and cognitive disturbance. Refer people with suspected mood disorders for formal psychological testing. (Panel consensus)
5. Assess functional status in the initial and subsequent patient visits. Measure the impact of FMS on physical and emotional function and overall quality of life. (Panel consensus)
6. Obtain a complete blood count and conduct erythrocyte sedimentation rate, muscle enzymes, liver function, and thyroid function tests in a new patient with probable FMS. (Panel consensus)

Interventions
7. Begin treatment of FMS by confirming the diagnosis of FMS and explaining what the condition is and what it is not. (Panel consensus) Patient education is critical to optimal management of FMS. (B)
8. Use multiple strategies and include both pharmacologic and nonpharmacologic therapies in the management of FMS. (A)

Pharmacologic Therapies
9. For initial treatment of FMS, prescribe a tricyclic antidepressant for sleep, in particular 10 to 30 mg amitriptyline or cyclobenzaprine at bedtime. (A)
10. Use selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, alone or in combination with tricyclics, for pain relief. (B) The doses of all antidepressants should be individualized and any concurrent mood disturbances treated. (Panel consensus)
11. Do not use non-steroidal anti-inflammatory drugs (NSAIDs) as the primary pain medication for people with FMS. (A) There is no evidence that NSAIDs are effective when used alone to treat FMS patients. NSAIDs, including COX-2 selective agents and acetaminophen, may provide some analgesia when used with other medications. (C)
12. Use tramadol (50 to 100 mg two or three times daily) for pain relief in people with FMS. The dose of tramadol should be increased slowly over time and should be tapered gradually when discontinued. Tramadol can be used alone or in combination with acetaminophen. (B)
13. Use opioids for management of FMS pain only after all other pharmacologic and nonpharmacologic therapies have been exhausted. (Panel consensus)
14. Use sleep and anti-anxiety medications such as trazodone, benzodiazepines, nonbenzodiazepine sedatives, or
L-dopa and carbidopa in FMS, especially if sleep disturbances such as restless leg syndrome are prominent. (A)
15. Do not use corticosteroids in the treatment of FMS unless there is concurrent joint, bursa, or tendon inflammation. (A)
16. Ask patients about their use of complementary products and practices and have sufficient knowledge of them to be able to answer questions concerning efficacy and identify possible negative interactions with prescribed treatment. (C)

Nonpharmacologic Therapies
17. Provide all patients with basic information on FMS and treatment options, and educate them about pain management and self-management programs as an initial part of treatment. (A)
18. Incorporate cognitive-behavioral therapy into a multimodality treatment approach to reduce pain, enhance self-efficacy, and improve function. (A)
19. Encourage and support people with FMS to perform moderately intense aerobic exercise (60-75% of age-adjusted maximum heart rate [210 minus the person’s age]) two to three times per week. (A) In individuals who are deconditioned, this rate can be achieved with very low levels of exercise.
20. Advise people with FMS to avoid exercise-induced pain by stretching to the point of slight resistance, not to the point of pain. This is especially important in subgroup of individuals who have joint hypermobility. (B)
21. Begin exercise programs for people with FMS at a level just below their capacity, and progress in frequency, duration, or intensity as their levels of fitness and strength increase. Exercise progression should be slow and gradual, or participants will experience a marked, exercise-induced exacerbation of pain that may lead to discontinuation of the exercise program. (Panel consensus)
22. Encourage people with FMS to perform muscle-strengthening exercise two times per week. (B)
23. Encourage ongoing exercise to maintain exercise-induced gains. (B)
24. Offer clinician-assisted treatments such as clinical hypnosis and biofeedback (B), acupuncture (C), chiropractic manipulation, therapeutic massage (B), and balneotherapy (A), which may be helpful for pain relief.
25. Use multidisciplinary approaches that incorporate two or more strategies to decrease pain and improve function in FMS, especially in people who have not responded to simpler approaches. (A)

Fibromyalgia Syndrome in Children and Adolescents
26. Assessment of pain in children with juvenile FMS (JFMS) should be developmentally based and should include both child and parent components. Include pain history, behavioral observation, physiologic cues, and evaluation of comorbid mood disorders, psychosocial distress, and functional status, including school attendance, for a comprehensive assessment. (Panel consensus)
27. Provide education for the child and family on the diagnosis of JFMS, interrelationship of symptoms, and management of symptoms. Provide education to the child and family on an ongoing basis to increase self-care skills, improve self-efficacy, and enhance understanding of the interrelationships between pain, mood, stress, exercise, and the role of factors concerning the parental and family environment. Include background information regarding the prevalence of pain in children. (Panel consensus)
28. Utilize pharmacologic and nonpharmacologic strategies in the management of JFMS. (Panel consensus)
29. Focus treatment on maximizing function, stressing the importance of regular school attendance. Set functional goals with the child and family. (Panel consensus)
30. Use cognitive-behavioral training (CBT) to reduce pain and psychological disability by enhancing self-efficacy, self-management, and skills for coping with pain. (Panel consensus)
31. Use aerobic exercise to minimize pain, improve sleep quality, enhance self-efficacy and increase positive mood. (Panel consensus)
32. Emphasize sleep hygiene as part of the treatment plan, using both pharmacologic and nonpharmacologic techniques. (Panel consensus)
33. Treat anxiety and depression aggressively with both pharmacologic and nonpharmacologic approaches. (Panel consensus)
34. Fluoxetine should be the first antidepressant agent used to treat depression in children and adolescents; however, all of these medications should be used only with extreme caution and extensive parental education. Psychiatric consultation is recommended. (Panel consensus)
35. Clinicians should focus on the goal of restoring function. The importance of continuing or returning to school cannot be overemphasized, and every effort should be made to maintain and maximize the child’s ability to attend school.

Definitions:
Type of Evidence
I. Meta-analysis of multiple well-designed controlled studies
II. Well-designed experimental studies
III. Well-designed, quasi-experimental studies, such as nonrandomized controlled, single-group pre-post, cohort, time series, or matched-case controlled studies
IV. Well-designed nonexperimental studies, such as comparative and correlational descriptive and case studies
V. Case reports and clinical examples

Strength and Consistency of Evidence
A. There is evidence of type I or consistent findings from multiple studies of types II, III, or IV.
B. There is evidence of types II, III, or IV, and findings are generally consistent.
C. There is evidence of types II, III, or IV, but findings are inconsistent.
D. There is little or no evidence, or there is type V evidence only.

Panel Consensus: Practice recommended based on the opinions of experts in pain management.

Clinical Algorithm(s)

The original guideline document contains algorithms for:
- Assessment of the Patient with Widespread Pain
- Treatment of Fibromyalgia Syndrome
- Pharmacologic and nonpharmacologic strategies in the management of the fibromyalgia syndrome
- Exercise programs for people with FMS

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The strength and consistency of the evidence supporting the recommendations ranges from A, which is the strongest evidence to D, which indicates there is little or no evidence, or that only type V (i.e., case reports and clinical examples) exists. In the absence of level A or B evidence, the panel used the available empirical evidence, but based its recommendation primarily on expert judgment. In these instances, the term, "Panel consensus," was used.

The type of evidence and/or expert judgment supporting each recommendation is identified and graded in the "Major Recommendations" field of this summary.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits
- Appropriate diagnosis and management of fibromyalgia syndrome
- Improved quality of care

Potential Harms

Refer to Tables 7 and 8 in the original guideline document for potential adverse effects of medications used to treat fibromyalgia syndrome.

Contraindications

Contraindications

The combination of hydrocodone with aspirin (Lortab ASA) is contraindicated in children in the presence of fever or other viral disease, because aspirin is associated with Reye's Syndrome.

Qualifying Statements

Qualifying Statements

- Any recommendations made by the authors must be weighed against the clinician's own clinical judgement, based on but not limited to such factors as the patient's condition, the benefits versus the risks of suggested treatment, and comparison with recommendations of pharmaceutical compendia and other authorities.
- No published reviews were found of fibromyalgia syndrome (FMS) pain in children and adolescents. The few published studies of FMS pain in children and adolescents are discussed in the section "Management of Pain in Juvenile Fibromyalgia Syndrome" of the original guideline document.
- Despite recognition of FMS as one of the most common chronic pain conditions, FMS continues to generate controversy. As noted earlier, much of the controversy is related to the diagnostic challenges and frustrations faced by clinicians and patients when dealing with symptoms that lack objective physical, laboratory, or radiologic evidence. Although many clinicians accept FMS as a common cause of chronic pain, they also recognize the subjectivity and lack of defining precision inherent in FMS.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Chart Documentation/Checklists/Forms
Clinical Algorithm

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.
Despite recognition of FMS as one of the most common chronic pain conditions, FMS continues to generate considerable interest. Antidepressant medication, such as tricyclic antidepressants (e.g., amitriptyline or cyclobenzaprine), is recommended for the treatment of FMS. Selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and paroxetine, or tricyclic antidepressants, are recommended for the management of comorbid mood disorders. Pain management strategies, including physical therapy, occupational therapy, and psychological services, are recommended. Physical therapy, including aerobic exercise, is recommended for the management of symptoms. Emphasize sleep hygiene as part of the treatment plan, using both pharmacologic and nonpharmacologic techniques. Encourage ongoing exercise to maintain exercise tolerance, and consider the use of nonsteroidal anti-inflammatory drugs (NSAIDs) in combination with other medication. Use sleep and anti-migraine medications as needed. Use tramadol (50 to 100 mg two or three times daily) for pain relief in people with FMS. The dose of tramadol should be titrated to clinical effect.

**Adaptation**

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

**Date Released**

2005

**Guideline Developer(s)**

American Pain Society - Professional Association

**Source(s) of Funding**

The following companies have contributed over the years to a common APS Guidelines Program Fund that is used for the support of all APS evidence-based clinical practice guidelines:

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- Knoll Laboratories
- McNeil Consumer Healthcare
- Merck and Co., Inc.
- Pain Therapeutics, Inc.
- Pharmacia and Upjohn
- Purdue Pharma L.P.
- Roxane Laboratories, Inc.

**Guideline Committee**


**Composition of Group That Authored the Guideline**

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All members of the Fibromyalgia Syndrome Pain Management Guideline Panel have submitted a Conflict of Interest Disclosure form, which is on file at the APS national office. In addition, panel members disclosed financial relationships with commercial companies to all other panel members during panel meetings.

Individual panel members presently have or during the past 3 years have had relationships with the following pharmaceutical or biotechnology companies:

Carol S. Burckhardt. Secondary data analysis: Astra Zeneca.

Leslie Crofford. Consultant: Eli Lilly, Pfizer; Speakers' Bureau: Cypress, Forest, Pfizer, Wyeth.


Kenneth Jackson. Consultant: Elan Pharmaceuticals; Research support: Elan Foundation, Merck Foundation; Speakers' Bureau: Merck, Ortho-McNeil, Pharmacia, Purdue Pharma L.P.

William McCarberg. Speakers' Bureau: Endo, Janssen Pharmaceuticals, Ligand, Purdue Pharma L.P.


Ada Jacox and Carol Spengler, APS consultants. Funding from the APS Guidelines Program Fund.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: None available at this time.


Availability of Companion Documents

Implementation tools, including manual tender point diagram and survey and examples of pain scales, are available in the original guideline document.

Electronic copies: None available at this time.


Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 27, 2005. The information was verified by the guideline developer on August 31, 2005. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on July 20, 2010 following the U.S. Food and Drug Administration advisory on Ultram (tramadol hydrochloride), Ultracet (tramadol hydrochloride/acetaminophen).

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