Complete Summary

GUIDELINE TITLE

AAOS clinical guideline on osteoarthritis of the knee.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Orthopaedic Surgeons. AAOS clinical practice guideline on osteoarthritis of the knee. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 17 p. [114 references]

GUIDELINE STATUS

This is the original release of this guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons. Clinical guideline on knee pain. Rosemont (IL): American Academy of Orthopaedic Surgeons; 1996. 12 p.

**** 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On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Subsequently, on April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their

products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web siteFDA Web site for more information.

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SCOPE

DISEASE/CONDITION(S)

Osteoarthritis of the knee

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Orthopedic Surgery
Physical Medicine and Rehabilitation
Rheumatology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To guide qualified physicians through a series of diagnostic and treatment decisions in an effort to improve the quality and efficiency of care in patients with osteoarthritis of the knee

TARGET POPULATION

- Adults (skeletally mature individuals) with confirmed osteoarthritis of the knee

Note: The guideline does not address the treatment of children or the skeletally immature.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

Differential diagnosis of osteoarthritis of the knee based on patient history and physical findings

Treatment/Management

1. Analgesics (e.g., acetaminophen) or nonsteroidal anti-inflammatory medication (NSAIDs), including cyclooxygenase-II (COX-II) inhibitors
2. Activity modification
3. Ongoing monitoring of complete blood count, renal and liver function tests, and stool guaiac
4. Ongoing assessment of response to treatment, with medication change as needed
5. Radiography, including standing anteroposterior (AP) view, lateral view, tangential view of the patella-femoral joint ("sunrise" view), and standing posteroanterior (PA) view
6. Patient education (counseling about weight loss, avoidance of aggravating activities, and support groups)
7. Use of durable medical equipment (e.g., assistive devices, modified footwear, bracing)
8. Physical therapy including general conditioning, muscle strengthening, and range of motion
9. Aspiration of synovial fluid to assess for infection
10. Arthrocentesis with intraarticular steroid injection
11. Viscosupplementation
12. Glucosamine and chondroitin sulfate treatment (considered but no recommendation given)
13. Referral to musculoskeletal specialist

MAJOR OUTCOMES CONSIDERED

- Patient satisfaction with treatment and progress
- Symptomatic relief (control of pain)
- Range of motion

- Physical functioning
- Complications associated with treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evaluation of Existing Guidelines: A search of MEDLINE, the National Guidelines Clearinghouse and the American Medical Association´s (AMA's) Clinical Practice Guidelines Directory (1999) was performed. Only one relevant guideline was located. The American College of Rheumatology Subcommittee on Osteoarthritis Guidelines: Recommendations for the medical management of Osteoarthritis of the Hip and Knee: 2000 Update, was reviewed by the work group.

Literature Review: A search of MEDLINE was performed in order to update the literature used to develop the original guideline. English language peer reviewed journals from 1990 to 2000; human studies of adults over 19 years of age were included.

NUMBER OF SOURCE DOCUMENTS

One hundred twenty-eight articles were identified and reviewed.

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

Type I. Meta-analysis of multiple, well-designed controlled studies; or high power randomized, controlled clinical trial.

Type II. Well-designed experimental study; or low-power randomized, controlled clinical trial.

Type III. Well-designed, non-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series.

Type IV. Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies.

Type V. Case reports and clinical examples.

Consensus/opinion *(as it is used in bibliography of the original guideline)*: Articles representing expert consensus and not meeting the rigid I-V measurement are noted to represent consensus/opinion.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus Development: The work group participated in a series of conference calls and meetings in which information was extracted and incorporated into the original algorithm. Information from the literature was supplemented by the consensus opinion of the work group, when necessary.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendation: The strength of the guideline recommendations for or against an intervention was graded as follows:

A. Type I evidence or consistent findings from multiple studies of types II, III, or IV

B. Types II, III, or IV evidence and findings are generally consistent

C. Types II, III, or IV evidence, but findings are inconsistent

D. Little or no systematic empirical evidence

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The participating societies and individuals conducted multiple iterations of written review. Modifications (when supported by references from the literature) were then incorporated by the workgroup chairman. The guideline was to be reviewed and approved by various groups within the American Academy of Orthopaedic Surgeons, including the Evidence Analysis Work Group, Evidence-based Practice Committee, Council on Research and Scientific Affairs, Board of Councilors, and Board of Directors, prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the ratings of the strength of recommendation (A-D) and the levels of evidence (Type I-Type V) are provided at the end of the "Major Recommendations" field.

Diagnosis

Osteoarthritis of the Knee

Definition of the Problem

Osteoarthritis of the knee is an increasingly common problem due to a more active society, often leading to prior knee injuries; an increasingly elderly population; and a growing percentage of the population that is overweight. Osteoarthritis of the knee should be suspected when a patient presents with knee pain that has been longstanding, increases with activity, particularly weight bearing and stairs, and improves with rest. Onset of pain and dysfunction is often insidious. Deformity, fixed contracture, crepitance and effusion are common findings. The differential diagnoses include inflammatory arthritis, bursitis or tendonitis, anterior knee pain and internal derangement.

Recommendations

For patients presenting to the first contact physician with knee pain, those with incapacitating instability, deformity or pain should be referred immediately to a musculoskeletal specialist. For the remainder, initial treatment should include activity modification and trial of an analgesic or non-steroidal anti-inflammatory medication (NSAID) **("A" recommendation)**. Acetaminophen has been shown to be as effective a pain reliever as NSAIDs in patients with osteoarthritis (OA) of the knee **("A" recommendation)**. Selective cyclooxygenase II (COX-II) inhibitors should only be used in those patients with renal or GI risk factors **("B" recommendation)**. Patients that respond well to initial treatment should be monitored. Those that use NSAIDs for 6 months should have a complete blood count (CBC), renal and liver function tests and a stool guaiac every 6 months **("D" recommendation)**. *See Note from NGC at the end of the "Major Recommendations" field.

Patients should be re-assessed within 1 to 4 weeks, based on the severity of the presenting problem. For patients that fail to respond to the initial treatment, or for whom pain returns, radiographs should be obtained **("D" recommendation)**. A

standing anteroposterior (AP) and a lateral view should be taken initially. A tangential view of the patella-femoral joint ("sunrise" view) and a standing posteroanterior (PA) view taken in 40 degrees of flexion can be useful **("B" recommendation)**. Radiographic feature of OA include: narrowing of the cartilage space, marginal osteophytes, subchondral sclerosis, and beaking of the tibial spines **("B" recommendation)**. For those patients with radiographic OA, subsequent treatment should include consideration of: changing to a different NSAID **("B" recommendation)**, patient education **("D" recommendation)**, physical therapy **("A" recommendation)**, and possibly durable medical equipment (DME) **("B" recommendation)**. Patient education includes counseling about weight loss, avoidance of aggravating activities, and support groups such as the Arthritis Foundation **("B" recommendation)**. Physical therapy should include general conditioning, muscle strengthening, particularly the quadriceps, and range of motion. Durable medical equipment that can reduce pain includes: assistive devices for ambulation such as a cane, appropriate and occasionally modified footwear, and bracing.

Patients should again be reassessed within 1 to 4 weeks. The final treatment intervention involves consideration of aspiration and cortisone injection **("D" recommendation)**. If the patient has an effusion and the physician is technically proficient at aspiration, the knee joint should be aspirated in a sterile manner, and the fluid sent for appropriate studies. If the synovial fluid does not show signs of hemarthrosis or infection, the knee joint should be injected with corticosteroid. If the physician is not technically proficient at arthrocentesis, or a hemarthrosis or infection is suspected or confirmed, referral to a musculoskeletal specialist is recommended. In patients without an effusion, a cortisone injection may be indicated if there are signs of inflammation such as: synovial thickening, pain that is diffuse or felt at night or rest, or improved with NSAIDs. Localized knee pain that is felt only with weight bearing is less likely to respond to cortisone injection.

Clinical Outcomes

Control of pain and maintenance of activity correlate well with satisfactory quality of life. If the patient is not satisfied with the outcome due to continued pain and limitation of activity, more aggressive intervention may be warranted. Referral to a musculoskeletal specialist is warranted.

Alternative Approaches

Viscosupplementation **("C" recommendation)** may have a role in the treatment of knee pain due to osteoarthritis during the initial 12 weeks in the hands of physicians technically proficient in arthrocentesis. The role of 'Chondroprotective' agents such as Glucosamine (GA) and Chondroitin Sulfate (CS) in treatment of osteoarthritis is not yet clear. There is a need for unbiased studies to clarify the issue.

Definitions:

Strength of Recommendation

A. Type I evidence or consistent findings from multiple studies of types II, III, or IV

B. Types II, III, or IV evidence and findings are generally consistent

C. Types II, III, or IV evidence, but findings are inconsistent

D. Little or no systematic empirical evidence

Levels of Evidence

Type I. Meta-analysis of multiple, well-designed controlled studies; or high power randomized, controlled clinical trial.

Type II. Well-designed experimental study; or low-power randomized, controlled clinical trial.

Type III. Well-designed, non-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series.

Type IV. Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies.

Type V. Case reports and clinical examples.

Consensus/opinion *(as it is used in bibliography of the original guideline)*: Articles representing expert consensus and not meeting the rigid I-V measurement are noted to represent consensus/opinion.

CLINICAL ALGORITHM(S)

A detailed algorithm is presented in the original guideline document on Universe of Adult Patients with Osteoarthritis of the Knee -- Phase I.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated and identified for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved medical care of adults with acute knee pain related to osteoarthritis of the knee

POTENTIAL HARMS

Risks and complications of treatment options (i.e., side effect profiles of analgesics and nonsteroidal anti-inflammatory drugs [NSAIDs]). Serious bleeding or renal dysfunction can occur with nonsteroidal anti-inflammatory drugs.

Subgroups of Patients Most Likely to Experience These Harms

Use of cyclooxygenase-II (COX-II) inhibitors is controversial in patients with known heart disease or hypertension. For certain high-risk patients, including pregnant women, nonsteroidal anti-inflammatory drugs (NSAIDs) are best avoided.

Risk factors for gastrointestinal or renal toxicity are as follows:

- Gastrointestinal risk factors: Age >65; history of peptic ulcer disease or gastrointestinal bleed; concomitant use of glucocorticoids or anticoagulants; smoking; significant ethanol use; comorbid medical conditions
- Renal risk factors: renal disease (creatinine >2.0); hypertension; congestive heart failure; concomitant use of diuretic or angiotensin-converting enzyme (ACE)-inhibitor

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

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
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Orthopaedic Surgeons. AAOS clinical practice guideline on osteoarthritis of the knee. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 17 p. [114 references]

ADAPTATION

The guideline was adapted from the 1996 American Academy of Orthopaedic Surgeons (AAOS) Clinical Guideline on Knee Pain, originally developed by a multi-professional panel led by the American Academy of Orthopaedic Surgeons Task Force on Clinical Algorithms in cooperation with the AAOS Committee on Clinical Policies, the American Association of Neurological Surgeons, the American College of Physical Medicine and Rehabilitation, the American College of Rheumatology, as well as individuals in other medical specialties including family practice.

DATE RELEASED

1996 (revised 2003)

GUIDELINE DEVELOPER(S)

American Academy of Orthopaedic Surgeons - Medical Specialty Society
American Association of Neurological Surgeons - Medical Specialty Society
American College of Physical Medicine and Rehabilitation - Professional Association
American College of Rheumatology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Orthopaedic Surgeons

GUIDELINE COMMITTEE

American Academy of Orthopaedic Surgeons (AAOS) Evidence-based Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of Revision Panel (1999-2003): Greg Stocks, MD, Chairman; Doug Dennis, MD; J. Wesley Mesko, MD; John A. Cardea, MD; Charles R. Clark, MD

Original Primary Authors (1996-1999): Aaron Rosenberg, MD, Chairman; Steven F. Harwin, MD; Thomas Sculco, MD; Doug Dennis, MD; Don Reilly, MD; Howard Fuchs, MD; Chuck Bush Joseph, MD; Calvin Brown, MD; Robert Barrack, MD; Ray Wasielewski, MD; Michael Kelly, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the original release of this guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons. Clinical guideline on knee pain. Rosemont (IL): American Academy of Orthopaedic Surgeons; 1996. 12 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Orthopaedic Surgeons Web site.

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: www.aaos.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Universe of adult patients with osteoarthritis of the knee -- Phase I. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 1 p.

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Orthopaedic Surgeons Web site.

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (847) 823-7186; (800) 346-AAOS. Fax: (847) 823-8125. Web site: www.aaos.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 15, 2000. The information was verified by the guideline developer on July 11, 2000. This summary was updated by ECRI on October 30, 2003. The information was verified by the guideline developer on November 5, 2003. This summary was updated by ECRI on January

12, 2005 following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of some non-steroidal anti-inflammatory drug products. This summary was updated on April 15, 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).

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