Complete Summary

GUIDELINE TITLE

Osteoporosis: prevention and treatment.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Osteoporosis: prevention and treatment. Ann Arbor (MI): University of Michigan Health System; 2005 Jul. 13 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Osteoporosis: prevention and treatment. Ann Arbor (MI): University of Michigan Health System; 2002 Mar. 12 p.

COMPLETE SUMMARY CONTENT

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

SCOPE

DISEASE/CONDITION(S)

Osteoporosis in postmenopausal women and secondary osteoporosis related to long-term glucocorticoid use, organ transplant, or other medical conditions

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention

Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To decrease osteoporotic fractures and their associated morbidity and mortality

TARGET POPULATION

Postmenopausal women and persons at risk for secondary osteoporosis related to long-term glucocorticoid use, organ transplant, or other medical conditions

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

1. Weight bearing exercise
2. Adequate dietary calcium and vitamin D
3. Regular physical activity
4. Avoid heavy alcohol consumption and smoking
5. Preventive use of bisphosphonates or calcitonin during glucocorticoid therapy

Risk Assessment and Diagnosis

1. Assessment of risk factors (e.g., age, smoking status, body weight, frailty, history of fracture, chronic glucocorticoid use, organ transplant status, other associated medical conditions and medications)
2. Dual emission X-ray absorptiometry (DEXA) measurement of bone mineral density (BMD)
3. Measurement of biochemical markers of bone resorption (considered but not recommended)
4. Evaluation for secondary causes of osteoporosis
5. Referral to specialists

Treatment/Management

1. Pharmacologic therapies
    - Calcium with vitamin D
    - Bisphosphonates such as alendronate or risedronate
    - Selective estrogen receptor modulators (SERMs) (e.g., raloxifene)

- Estrogen or hormone replacement therapy (HRT) (i.e., estrogens [estradiol, esterified estrogens, estropipate, conjugated estrogens, transdermal estradiol]; progestins [medroxyprogesterone, micronized progesterone]; combined estrogen with progestin)
- Calcitonin nasal spray

Considered but not necessarily recommended at this time:

- Combined estrogen and bisphosphonate
- Testosterone replacement or supplement in men
- Calcitriol
- Tamoxifen
- Thiazide diuretics (e.g., hydrochlorothiazide)
- HMG-coA-reductase inhibitors (statins)
- Phytoestrogens

2. Non-pharmacologic therapies
    - Weight bearing or balance exercises
    - Fall prevention measures
    - Anatomically designed hip protectors

Follow-up

Repeat DEXA measurement

MAJOR OUTCOMES CONSIDERED

- Risk for osteoporosis or osteoporotic fractures
- Incidence of osteoporosis or osteoporotic fractures
- Bone mineral density, bone turnover and loss
- Predictive value of diagnostic tests
- Mortality related to osteoporotic hip fractures
- Morbidity (chronic pain, disability, deformity, depression) related to osteoporotic fractures
- Pain relief
- Medication side effects

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 literature search for this project started with the results of a literature search performed by the National Osteoporosis Foundation (Osteoporosis: review of the evidence for prevention, diagnosis and treatment and cost-effectiveness analysis), published in 1998 and including literature through 1996. We searched subsequent

literature. The search was conducted prospectively using the major key words of: *osteoporosis* (or *osteoporosis*, *postmenopausal*); *osteopenia*; either *hip fractures* or *spinal fractures* with either *osteoporosis* or *osteopenia*; English language; *cost savings*, *cost and cost analysis*; *sensitivity and specificity*, *false negative reactions*, *false positive reactions*, *likelihood functions*, *sensitivity*, *diagnosis*; *clinical protocols*, *physician's practice patterns*, *algorithms*, *outcome and process assessment (health care)*, *consensus development conferences*, *practice guidelines*, *guideline*; *clinical trials*, *clinical trials phase IV*, *controlled clinical trials*, *multicenter studies*, *randomized controlled trials*, *cohort studies*. Specific searches were performed for (1) *postmenopausal osteoporosis* (1996-99), for (2) *steroids* (1994-99), and for *organ transplantation*, *transplantation* (1990-99) with each of the following: *densitometry x-ray*, *bone density*, *absorptiometry photon*; *calcium*, *calcium carbonate*, *calcium citrate*; *Vitamin D*; *estrogens*, *progestational hormones*, *androgens*, *estrogen replacement therapy*; *diphosphonates*; *tamoxifen*; *piperidines*; *calcitonin*; *exercise*; *accident prevention*. Searches were also performed for *men*, *male*; *alternative medicine*, *isoflavones*; *alkaline phosphatase*, *hydroxyproline*, *osteocalcin*, *bone marker*, *bone and bones*; *osteopenia* (1990-99).

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

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

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trails if available, to the exclusion of other data. If randomized controlled trials were not available,

observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences

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

University of Michigan Health System (UMHS) guidelines are reviewed by leadership and in clinical conferences of departments to which the content is most relevant. This guideline concerning knee pain was reviewed by members of the following departments or divisions: Endocrinology Family Medicine, General Medicine, and Obstetrics/Gynecology, Guidelines are approved by the Executive Committee for Clinical Affairs.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information on drug dosing, Dexa-T scoring, and patient screening criteria.

The levels of evidence (A, B, C, D) are repeated at the end of the "Major Recommendations" field.

Definitions

- *Bone mineral density* (BMD) correlates with skeletal strength and fracture risk.

- *Dual emission X-ray absorptiometry* (DEXA) measures BMD.
- A DEXA *T-score* is the number of standard deviations from mean BMD in young adult women.
- *Osteoporosis* is defined as a DEXA T-score $\leq$-2.5, *osteopenia* as >-2.5 but <-1.0 (refer to Table 1 in the original guideline document for details).

General Clinical Relevance

Fractures related to osteoporosis are common and have high morbidity *[C]*.

Glucocorticoids can cause significant bone loss, particularly during the first 6 to 12 months of use *[C]*.

Prevention

Recommend weight bearing exercise and adequate calcium (1200-1500 mg/day) and vitamin D (400-800 IU/day) across the life span (refer to Table 6 in the original guideline document for details) *[D]*. Most older persons need vitamin D 700-800 IU/day *[A]*.

Risk Assessment and Diagnosis

- Assess all adults for clinical risk factors for osteoporotic fracture (refer to Table 2 in the original guideline document for details) *[C]*
    - Postmenopausal woman with one or more of the following:
        - Age $\geq$65 years
        - Current smoking
        - Low body weight
        - Frailty
        - Personal history of fracture without substantial trauma age $\geq$40
        - Hip, wrist, or spine fracture without substantial trauma in 1st degree relative $\geq$50
    - Chronic glucocorticoid use (prednisone $\geq$7.5 mg daily, or equivalent, for $\geq$6 months)
    - Organ transplant or pending transplant
    - Other associated medical conditions and medications
- Order DEXA based on clinical risk factors and potential impact of results on management (refer to Table 3 in the original guideline document for details).
- Evaluate appropriately and refer, when indicated, for secondary causes of osteoporosis (refer to Table 4 in the original guideline document for details) *[D]*.

Treatment

- Treat based on DEXA T-score and clinical risk factors for fracture (refer to Table 2 and Table 6 in the original guideline document for details)
    - Prior osteoporosis-related fracture *[A]*.
    - T-score $\leq$-1 and (a) glucocorticoid use or (b) pending or post-transplant, especially if on steroids or (c) postmenopausal woman at high risk (i.e., with other risk factors for fracture but not already receiving hormone replacement therapy [HRT] *[A]*).

    - T-score <-2 and (a) postmenopausal woman *[A]* or (b) man *[A]* or (c) person with other risk factors *[D]*.
- When starting glucocorticoids consider therapy for prevention or treatment of osteoporosis *[A]*.
- Base management strategies on benefits and risks (refer to Table 6, Table 7, and Table 8 in the original guideline document for details)
    - In post-menopausal women with osteoporosis:
        - Alendronate and risedronate reduce hip and vertebral fracture risk *[A]*.
        - Raloxifene and calcitonin reduce vertebral fracture risk *[A]*.
        - HRT reduces vertebral *[A]* and hip *[A]* fracture risk, but overall poses health risks ≥placebo *[A]*. Consider use of HRT for osteoporosis only if there are other indications to use HRT.
    - In men with osteoporosis, alendronate reduces vertebral fracture risk *[A]*.
    - In glucocorticoid use, risedronate (and perhaps alendronate) reduces vertebral fracture risk *[A]*.

Follow-up

- Follow-up osteoporosis or osteopenia with a repeat DEXA based on a patient's situation (refer to Table 3 and Table 5 in the original guideline document for details).
- For most persons an interval of ≥2 years between DEXAs provides the most meaningful information.
- Early in glucocorticoid use and/or after transplantation consider repeating DEXA in 6 to 12 months.

Definitions:

Levels of Evidence

Levels of evidence reflect the best available literature in support of an intervention or test.

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

Conclusions were based on prospective randomized clinical trials, if available, to the exclusion of other data. If randomized controlled trials (RCTs) were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

- Improved identification of patients at high risk for osteoporosis
- Decreased incidence of osteoporotic fractures and associated morbidity and mortality

POTENTIAL HARMS

Drug Therapies

- *Calcium*: Constipation is common.
- *Bisphosphonates*: Mild gastrointestinal effects and rare severe gastrointestinal effects. Safety is not known for women during childbearing years
- *Raloxifene*: Risk of deep venous thrombosis and pulmonary embolism approximately the same as hormone replacement therapy; hot flashes
- Side effects of *calcitriol or high doses of other forms of vitamin D* include hypercalcemia, hypercalciuria, and nephrolithiasis, and therefore serum and urinary calcium levels must be monitored by a subspecialist or others familiar with their use.
- In the Women's Health Initiative (WHI) *estrogen combined with progestin* was associated with an increased risk of coronary heart disease, stroke, invasive breast cancer, and venous thromboembolism. In the same study, estrogen alone compared to placebo was associated with an increased risk of stroke and deep venous thrombosis (but not pulmonary embolus).
- In an ancillary study, Women's Health Initiative Memory Study (WHIMS), there was a small increase in risk of dementia and mild cognitive impairment for those women over age 65 who took *estrogen*, either combined or alone, compared to placebo.
- WHI data and other studies suggest that *HRT* raises risk for gall bladder disease, specifically cholelithiasis, cholecystitis, and cholecystectomy. Also, (contrary to common belief) HRT seems to be associated with increased risk of new urinary incontinence or worsening of existing urinary incontinence. Estrogen alone for a woman with a uterus increases the risk of endometrial cancer, although adding a progestin reduces the risk to baseline.
- *Calcitonin*: Rhinitis has been observed in 5% excess compared with placebo. Caution is urged with calcitonin nasal spray in renal failure.
- *Tamoxifen*: May cause a significant decrease in BMD in premenopausal women (due to interference with estrogen).

Non-drug Therapies

Anatomically designed hip protectors: Patient discomfort and concern about appearance limit compliance.

CONTRAINDICATIONS

CONTRAINDICATIONS

Bisphosphonates

Reflux without esophagitis is a relative but not an absolute contraindication. Bisphosphonates should be avoided if creatinine clearance is <30 to 35.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Staff Training/Competency Material

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
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Osteoporosis: prevention and treatment. Ann Arbor (MI): University of Michigan Health System; 2005 Jul. 13 p.

ADAPTATION

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

DATE RELEASED

2002 Mar (revised 2005 Jul)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Osteoporosis Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Osteoporosis: prevention and treatment. Ann Arbor (MI): University of Michigan Health System; 2002 Mar. 12 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following are available:

- Osteoporosis in women. University of Michigan Health System; 2005 Jul. Various p. Electronic copies: Available from the University of Michigan Health System Web site. Also available in Spanish from the University of Michigan Health System Web site.
- Calcium and vitamin D. University of Michigan Health System; 2005 Jul. Various p. Electronic copies: Available from the University of Michigan Health System Web site. Also available in Spanish from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 19, 2003. The information was verified by the guideline developer on April 23, 2003. This NGC summary was updated by ECRI on September 22, 2005. The updated information was verified by the guideline developer on November 1, 2005.

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