Complete Summary

GUIDELINE TITLE

Osteoporosis. Guide to prevention, diagnosis, and treatment.

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Osteoporosis. Guide to prevention, diagnosis, and treatment. Boston (MA): Brigham and Women's Hospital; 2001. 11 p. [13 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Physical Medicine and Rehabilitation
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide physicians with clear clinical pathways to prevent, diagnose, and treat osteoporosis

TARGET POPULATION

- Women of all ages (universal prevention recommendations)
- Postmenopausal women (diagnosis and treatment recommendations)

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention, Diagnosis and Treatment of Osteoporosis

1. Modification of nutritional and lifestyle factors, including calcium and vitamin D intake, exercise, smoking, and alcohol consumption
2. Assessment of risk factors
3. Bone mineral density (BMD) testing using dual X-ray absorptiometry of the spine, hip, or forearm
4. Antiresorptive therapy, including estrogen (e.g., Estrace, Premarin), alendronate (Fosamax), risedronate (Actonel), raloxifene (Evista), and calcitonin (Micalcin)

MAJOR OUTCOMES CONSIDERED

- Bone density
- Osteoporotic fracture risk

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches using Medline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed by the Brigham and Women's Hospital Osteoporosis Guideline Review Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Clinical Strategy

Assessing Women's Risk

With advancing age and the postmenopausal decline of estrogen, women are at increased risk for osteoporosis (defined as low bone mass that leads to skeletal fragility and fracture).

The decision to use hormone replacement therapy (HRT), however, must be made within the context of many complex factors--the individual woman's risk of cancer, her desire to relieve menopausal symptoms, and the potential benefits of reducing the risk of osteoporosis. Once the decision about HRT is made for the individual patient, there are different clinical pathways for preventing, detecting, and treating osteoporosis.

Major Risk Factors

Bone mineral density testing should be considered for all postmenopausal patients with one or more of the following major risk factors, particularly women not on hormone replacement therapy (HRT):

- Family history of osteoporosis (first-degree relative)
- Body mass index (BMI) is below the 25th percentile, i.e., 22 kg/m^2 (e.g., <127 lb at 5'4")
- History of bone fracture as an adult
- Current cigarette smoking

Other Risk Factors

Physicians should use clinical discretion to assess the impact of the following risk factors (in addition to female sex) on bone health and the need for bone mineral density (BMD) testing:

- Lifelong low calcium intake
- Caucasian race
- Inadequate physical activity
- Recurrent Falls
- Estrogen deficiency
    - Menopause at age <45
    - Premenopausal amenorrhea >1 year
- Advanced Age
- Excessive alcohol
- Dementia
- Poor health/frailty

Clinical Pathways

Lifelong Evaluation

As supported by research studies, the clinical pathways for preventing and treating osteoporosis are differentiated into three distinct groups:

Childhood to Menopause

Discuss Universal Prevention Strategies

Beginning with young women, discuss the nutritional and lifestyle factors that promote bone health and help prevent osteoporosis: calcium, vitamin D, weight-bearing exercise, and avoidance of smoking and excessive alcohol (see "Bone

Health: Universal Recommendations" below). A strategy begun in early adulthood will have a major impact on bone density later in life.

Menopause to 64

Assess Risk Factors

In guiding clinical decisions for postmenopausal women, physicians should assess each patient's risk factors, which determine the need to obtain a baseline BMD. Universal strategies to prevent osteoporosis should be encouraged.

Age 65 and Older

Perform BMD Testing

For this age group, women are at increased risk for fracture. A baseline BMD is recommended for all patients, regardless of hormone therapy. Universal strategies should be encouraged.

Refer to the original guideline document for the algorithm, "Evaluation and Treatment of Osteoporosis."

Secondary Causes

Low bone mass may result from secondary causes. A thorough history and physical should be performed to identify potential secondary causes. As appropriate, care of such patients should be done in consultation with specialists in skeletal health. Secondary causes of osteoporosis include a broad range of disease states and drugs, as partially listed below.

Endocrine and Metabolic Abnormalities

Acromegaly, Cushing's syndrome, hypercalciuria, hyperparathyroidism, hyperthyroidism, hypogonadism including anorexia nervosa, prolactinoma, renal tubular acidosis, type 1 diabetes mellitus, vitamin D deficiency

Hematologic Disorders

Gaucher's disease, hemophilia, homocysteinuria, leukemia, lymphoma, multiple myeloma, pernicious anemia, thalassemia

Immobilization

Immobilization

Gastrointestinal Disease

Celiac disease, chronic liver disease, gastrectomy, hemochromatosis, inflammatory bowel disease, parenteral nutrition, primary biliary cirrhosis

Connective Tissue Abnormalities

Amyloidosis, Ehler-Danlos syndrome, Marfan's syndrome, osteogenesis imperfecta

Rheumatologic Disorders

Ankylosing spondylitis, rheumatoid arthritis

Drugs

Adrenocorticotropin, alcohol (excessive), anticonvulsants, cyclophosphamide, cyclosporine, glucocorticosteroids, heparin, lithium, methotrexate, tamoxifen (premenopausal), thyroxine (supraphysiologic doses)

Bone Mineral Density Testing

Bone mineral density (BMD) is a useful tool to assess bone health and guide clinical interventions to prevent low bone mass (osteopenia) from progressing to osteoporosis. BMD can be measured rapidly and reproducibly with little radiation exposure using dual X-ray absorptiometry of the spine, hip, or forearm. Result is reported as Z-score and T-score.

Whom to Test

- Postmenopausal women to age 64
    - Not on HRT and having at least one major risk factor for osteoporosis
    - History of fracture (excluding major trauma, e.g. motor vehicle accident [MVA]) as an adult
    - Discretionary for others (see the algorithm, "Evaluation and Treatment of Osteoporosis" in the original guideline document)
- All women age 65 and older

Interpreting BMD Results

T-Score

Patient's BMD is compared with "young normal" adults of same sex; result is expressed as the number of standard deviations (SD) above or below the mean (example: T-score of -2.0 is 2 SDs below the mean).

- Above -1: Normal- continue with prevention strategies.
- Between -1 and -2.5: Osteopenia- see "Management Recommendations" below

Z-Score

Patient's BMD is compared with persons of same age and sex.

- Below -1.5: Consider possible secondary cause of osteoporosis. Reasonable secondary workup--CBC, serum Ca, 25 OH-vitamin D level, and thyroid-stimulating hormone (TSH).

Bone Health

Universal Recommendations for All Women

Calcium

- Menarche to age 18: 1,300 mg/day
- Age 19 to menopause: 1,000 mg/day
- Postmenopause: 1,200 mg/day

Dietary Sources

Note: Most Americans get 400-800 mg calcium from diet, primarily from dairy sources.

- Yogurt (8 oz): 300 mg (fruit); 400 mg (plain)
- Milk (8 oz): 300 mg
- Cheese slice (1 oz): 200 mg
- Calcium fortified cereals and juices are available.

Supplements

To maximize efficacy, split daily intake (e.g., <500 mg twice per day)

- Calcium carbonate: 500-600 mg (e.g., Oscal/Oscal D, Caltrate/Caltrate D, generic; Tums = 200-500 mg) Requires acid stomach for absorption; take with meals to avoid gastric distress.
- Calcium citrate: 200-315 mg (e.g., Citrical/Citrical D) Better absorbed, fewer side effects, but more expensive.

Vitamin D

400-800 IU/day

400 IU is usual dose in multivitamins; for more, take vitamin D supplement or combined calcium-vitamin D supplement (e.g., Caltrate D, Citrical D, generic). Fortified milk (8 oz) contains 100 IU. For patients with no vitamin D deficiency, upper safety limit is 2,000 IU/day; patients with vitamin D deficiency require higher doses.

Exercise

Weight-bearing and strength-training (upper and lower body)

- Includes walking, jogging, stair climbing, dancing, tennis, and weight-lifting.
- Continuous activity for 40 minutes at least two times per week.

Smoking

Avoid cigarette smoking

Alcohol

Avoid excessive alcohol

Low bone density in alcohol-dependent women has been documented, but the daily amount of alcohol intake that increases osteoporosis risk is undetermined. Advice on alcohol should be balanced with research that suggests >1 drink/day increases risk of breast cancer; 2 drinks/day (upper limit) protects against cardiovascular disease.

Management Recommendations

Prevention of Osteoporosis

T-score between -1 and -2.5

- Review daily intake of calcium (1,200 mg) and vitamin D (400-800 IUs)
- Review weight-bearing exercise, avoiding smoking and excessive alcohol
- Consider preventive therapy with antiresorptive agent (i.e., estrogen, alendronate, risedronate, raloxifene; refer to Table 1 in the original guideline document for details); for patients already on hormone replacement therapy (HRT), consider alternative therapy or possible combination

Treatment of Osteoporosis

T-score below -2.5

- Review daily intake of calcium (1,200 mg) and vitamin D (400-800 IUs)
- Review weight-bearing exercise, avoiding smoking and excessive alcohol
- Initiate osteoporosis therapy (i.e., alendronate, risedronate, calcitonin, raloxifene; refer to Table 2 in the original guideline document for details)

Follow-up for Osteopenia and Osteoporosis

- Annual visit; review nutritional and lifestyle guidelines
- Confirm compliance with therapy (50% or more discontinue hormone replacement therapy within 1 yr)
- Repeat bone mineral density (BMD) in 12-24 months; subsequently at physician's discretion
- If bone mineral density is falling and antiresorptive therapy was not initiated in osteopenia setting, reconsider antiresorptive therapy

Indications for Referral to Specialist

- Secondary causes of osteoporosis
- Contraindications to standard osteoporosis therapy
- Bone loss on osteoporosis therapy

- Fracture on osteoporosis therapy
- Complex medical history

CLINICAL ALGORITHM(S)

An algorithm is provided for the evaluation and treatment of osteoporosis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Guideline recommendations are based on a comprehensive assessment of research on osteoporosis and the 1998 recommendations of the National Osteoporosis Foundation (NOF).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention and Effective Treatment of Osteoporosis

- Estrogen. Prophylactic estrogen therapy is expected to increase bone density. The cardiac benefit of estrogen therapy is uncertain: observational studies suggest reduction in myocardial infarction, but recent randomized trial showed no benefit. Estrogen improves symptoms of estrogen deficiency (e.g., hot flashes). Observational studies suggest that estrogen possibly reduces the risk of colorectal cancer and Alzheimer's disease but further study in randomized controlled trials are needed.
- Alendronate. Prophylactic alendronate is expected to increase bone density. Alendronate therapy reduces vertebral fracture risk by 48% and hip fracture risk reduction is 51% in women with osteoporosis and previous vertebral fracture.
- Risedronate. Prophylactic risedronate is expected to increase bone density. Risedronate therapy reduces the risk for hip fracture by 40 to 50% in women with osteoporosis and previous vertebral fracture.
- Raloxifene. Prophylactic raloxifene is expected to increase bone density. Raloxifene therapy in the woman with osteoporosis reduces vertebral (but not hip) fracture risk 30 to 50%. Early data suggest significant (> 50%) reduction in risk of breast cancer and no endometrial stimulation (do not need progestin).
- Calcitonin. In the treatment of osteoporosis calcitonin is expected to reduce vertebral fracture risk 33%; there is no significant reduction in hip fracture or other non-vertebral fractures. Calcitonin may also have a beneficial analgesic effect.

Subgroups Most Likely to Benefit:

Patients with previously undiagnosed or untreated secondary causes of low bone mass

POTENTIAL HARMS

Side Effects/Risks Associated with Specific Agents

- Estrogen. Endometrial hyperplasia or cancer (hence need to take with progestin if uterus present); vaginal bleeding; breast fullness/tenderness; deep venous thrombosis (DVT)/pulmonary embolism (PE); Increased risk for breast cancer with long term use.
- Alendronate. Esophagitis/upper gastrointestinal (GI) distress; myalgia/arthralgias.
- Risedronate. Upper GI distress; myalgia; arthritis.
- Raloxifene. May increase hot flashes.
- Calcitonin. Rhinorrhea.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to Specific Agents

- Estrogen. History of deep vein thrombosis or pulmonary embolism; significant hypertriglyceridemia; caution should be exercised for personal or family history of breast cancer.
- Alendronate. Active upper gastrointestinal disease; history of esophageal abnormalities; achalasia; reflux esophagitis (relative contraindication); renal impairment.
- Risedronate. History of esophageal abnormalities, achalasia, esophagitis (relative contraindication); renal impairment.
- Raloxifene. History of deep vein thrombosis or pulmonary embolism; hot flashes.
- Calcitonin. Allergy to calcitonin.

QUALIFYING STATEMENTS

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- This guide is not intended to convey rigid standards, but instead, should be tailored to the needs of each individual woman.
- This guideline is intended for general educational purposes for the benefit of health care professionals. It is not intended for use by patients. Brigham and Women's Hospital encourages patients to contact a qualified health care professional for answers to personal questions about their diagnosis, care, and treatment.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

As approved by the Network Medical Management Group, the guideline is incorporated into appropriate Continuing Medical Education (CME) courses, Grand Rounds, and Case Discussion Sessions.

Electronic medical reminders to physicians within the institution are in development.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Osteoporosis. Guide to prevention, diagnosis, and treatment. Boston (MA): Brigham and Women's Hospital; 2001. 11 p. [13 references]

ADAPTATION

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

DATE RELEASED

1999 (revised 2001)

GUIDELINE DEVELOPER(S)

Brigham and Women's Hospital (Boston) - Hospital/Medical Center

SOURCE(S) OF FUNDING

Funding was provided by Brigham and Women's Hospital.

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: LeBoff MS, Bermas B, Dunaif A, Gharib S, Fairchild DG, Ginsburg E, Johnson PA, Soloman CG. Osteoporosis: guide to prevention, diagnosis, and treatment. Boston (MA): Brigham and Women's Hospital; 1999. 9 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Brigham and Women's Hospital Web site.

Print copies: Available from the Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; telephone: (800) BWH-9999; Web site: www.brighamandwomens.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Healthy bones for life. Prevention, diagnosis and treatment for osteoporosis. Boston (MA): Brigham and Women's Hospital. 2002. 14 p.

Electronic copies: Available in Portable Document Format (PDF) from the Brigham and Women's Hospital Web site.

Print copies: Available from the Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; telephone: (800) BWH-9999; Web site: www.brighamandwomens.org.

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 summary was completed by ECRI on January 7, 2000. The information was verified by the guideline developer on February 7, 2000. This summary was updated by ECRI on January 28, 2003. The information was verified by the guideline developer on February 10, 2003.

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