



Guideline Summary NGC-9312

Guideline Title

Osteoporosis.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2012 Sep. 17 p. (ACOG practice bulletin; no. 129). [78 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Jan. 14 p. (ACOG practice bulletin; no. 50). [78 references]

Scope

Disease/Condition(s)

Osteoporosis and osteoporotic fractures

Guideline Category

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

Clinical Specialty

Family Practice
Geriatrics
Internal Medicine
Nutrition
Obstetrics and Gynecology
Preventive Medicine
Radiology

Intended Users

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

Guideline Objective(s)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the diagnosis, evaluation, and treatment of osteoporosis

Target Population

- Adolescent and adult women (*counseling*)
- Women 65 years of age or older (*screening*)
- Postmenopausal women with or at risk of developing osteoporosis (*screening, prevention, treatment*)

Interventions and Practices Considered

Screening/Diagnosis/Evaluation/Risk Assessment

1. Bone mineral density testing using dual-energy x-ray absorptiometry (DXA) of the lumbar spine and hip
2. Other bone densitometry technologies: peripheral DXA of the heel, finger, or wrist; quantitative ultrasound densitometry; quantitative computed tomography (considered but no recommendation made)
3. Vertebral fracture assessment
4. Medical history of low-trauma fracture in an at-risk woman
5. Biochemical markers of bone turnover (considered but no recommendation made)
6. Risk assessment of osteoporotic fracture using fracture risk assessment tool (FRAX)
7. Evaluation for secondary causes of osteoporosis

Prevention/Treatment/Management

1. Counseling regarding lifestyle change, including weight-bearing and muscle strengthening exercises, adequate calcium and vitamin D consumption, proper nutrition, smoking cessation, moderation of alcohol consumption, and fall prevention strategies
2. Hormone therapy (estrogen therapy or combined estrogen and progestogen therapy)
3. Bisphosphonates (alendronate, risedronate, ibandronate, and zoledronate)
4. Raloxifene
5. Denosumab
6. Calcitonin
7. Human recombinant parathyroid hormone
8. Treatment initiation and monitoring frequency

Major Outcomes Considered

- Bone mineral density
- Fracture rates
- Loss of function
- Mortality and morbidity

Methodology

Methods Used to Collect/Select the 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 MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1990 and March 2012. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

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

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Level C recommendations.

Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

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

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Recommendations

Major Recommendations

The grades of evidence (**I-III**) and levels of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Treatment should be recommended for:
 - Women with a T-score of -2.5 or less
 - Women who have had low-trauma fracture
 - Women who have a T-score from -1 to -2.5 and a fracture risk assessment tool (FRAX) score greater than or equal to 3% for risk of hip fracture or a FRAX score greater than or equal to 20% for risk of a major osteoporotic fracture (defined as forearm, hip, shoulder, or clinical spine fracture) or both in the next 10 years.
- U. S. Food and Drug Administration (FDA)-approved therapies should be used for medical treatment: raloxifene, bisphosphonates, parathyroid hormone (PTH), denosumab, calcitonin.

- Bone density screening for women should begin at age 65 years. Dual-energy X-ray absorptiometry screening can be used selectively for women younger than 65 years if they are postmenopausal and have other significant risk factors for osteoporosis or fracture.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- In the absence of new risk factors, dual-energy X-ray absorptiometry (DXA) screening should not be performed more frequently than every 2 years.
- In the absence of new risk factors, DXA monitoring of therapy should not be repeated once bone mineral density (BMD) has been determined to be stable or improved.
- Women should be counseled about lifestyle factors that may affect BMD and fracture risk: smoking, poor nutrition and excessive weight loss, weight-bearing and muscle-strengthening exercise, and fall-prevention measures.
- Women should be advised of current Institute of Medicine (IOM) calcium and vitamin D recommendations.

The following conclusion is based primarily on consensus and expert opinion (Level C):

- The effect of lifestyle on bone health should be considered for girls and women of all ages and they should be counseled accordingly.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

An algorithm for screening and treating postmenopausal women for fracture prevention is provided in the original guideline document (Figure 2).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

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

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate screening, prevention, and treatment of osteoporosis

Potential Harms

Bisphosphonates

- Zoledronate is contraindicated in patients with acute renal failure or creatinine clearance of less than or equal to 35 mL/min. Patients should be screened for renal disease before zoledronate infusion because renal failure has occurred after infusion in patients with compromised renal function. Caution with regard to renal function should be exercised with other drugs in this class as noted in the product information sheets. Hypocalcemia should be corrected before the use of these drugs.
- Other adverse effects of bisphosphonates include musculoskeletal aches and pains, gastrointestinal irritation, and esophageal ulceration. Potential risks reported after marketing include osteonecrosis of the jaw, seizures, atypical fractures of the femoral shaft, and esophageal cancer. A precise understanding of the true risk of these events has been difficult to determine because of the lack of data on the incidence of these problems in the general population. Although rare cases of osteonecrosis of the jaw have been reported in patients using bisphosphonates for osteoporosis, it has been seen most commonly after dental extractions in those being treated with large intravenous doses of bisphosphonates in association with supportive cancer therapy. There is no requirement to discontinue bisphosphonates for dental procedures. However, there is likely to be no harm in discontinuing a bisphosphonate temporarily for a dental procedure, if the patient so desires, given the long duration of action of bisphosphonates.

Note: It is not yet known if there should be a limit to the duration of use of bisphosphonates. An advisory panel to the U.S. Food and Drug Administration reviewed the issue of treatment interruption (drug holidays) and duration of therapy and recommended that labeling be more

specific with regard to duration of use. In practice, despite lack of evidence or labeling guidance, there seems to be a trend toward offering treatment interruption after 5–10 years of use.

Partial Estrogen Agonists and Antagonists

Adverse effects of raloxifene include venous thromboembolism, leg cramps, and death from stroke (not increased risk of stroke). A medical history of stroke should be carefully weighed when considering use of this drug. Women close to menopause may experience vasomotor symptoms for a while after initiating therapy.

Denosumab

A higher rate of infections that required hospitalization was seen in the clinical trials. However, concerns about suppression of the immune system leading to increased rates of cancer were not substantiated.

Calcitonin

Adverse effects include flushing and nausea with subcutaneous injection and local irritation with nasal spray.

Recombinant Human Parathyroid Hormone (PTH)

- Treatment is restricted to 2 years because of research in laboratory rats that found an increased incidence of osteosarcoma with high-dose treatment. Because of this finding, it is recommended that teriparatide not be used in women with bone metastases or Paget disease of the bone or women who have had skeletal irradiation.
- Adverse effects include nausea, dizziness, muscle cramps, and infrequent hypercalcemia. Fracture reduction was demonstrated in vertebral and nonvertebral categories. Bone mineral content is lost quickly after discontinuation of PTH. Studies have demonstrated the importance of adding an antiresorptive agent after discontinuation of PTH.

Hormone Therapy

Current data suggest that combined estrogen and progestogen therapy can be used for 3–5 years before encountering an increased risk of breast cancer. Estrogen therapy can be used for a longer period of time, in the absence of other risk factors because of the delayed risk of breast cancer seen with estrogen therapy (approximately 15 years according to the Nurses' Health Study). Thus, the clinician must work closely with the patient to determine what is in her best interest because risks of hormone therapy are smallest in the younger postmenopausal woman and increase with age.

Vitamin D and Calcium

- There is emerging evidence of a U-shaped curve with respect to risks associated with vitamin D. Both low and high levels appear to carry risks. These risks include cardiovascular disease, some types of cancer, falls, fractures, and all-cause mortality. The Institute of Medicine (IOM) recommended upper limit of vitamin D intake for adolescents and adults is 4,000 international units/d.
- High intake of calcium also has been associated with risks. A 2009 Cochrane analysis of 11 trials reported a statistically significant increase in renal stones or renal insufficiency (relative risk, 1.16; 95% confidence interval, 1.02–1.33). Controversy exists regarding the possible association of calcium supplementation and coronary artery calcification and coronary artery events. In a secondary analysis of a randomized controlled trial designed to assess the effect of calcium supplements on bone, a trend toward an increase in cardiovascular events was noted. In a reanalysis of the Women's Health Initiative (WHI) data that involved only those participants who were not using personal calcium supplements at randomization, the authors found a statistically significant increase in cardiovascular events in those women randomized to calcium supplementation. The authors recommended dietary sources of calcium as potentially safer sources of calcium than supplements. Other reports, including a meta-analysis, dispute the findings and report no beneficial or detrimental effects to the cardiovascular system.

Contraindications

Contraindications

Bisphosphonates (Oral)

- Abnormalities of the esophagus
- Inability to stand or sit upright for at least 30 minutes
- Hypersensitivity to any component of this product
- Hypocalcemia
- Patients at increased risk of aspiration should not receive Fosamax oral solution

Zoledronic Acid (Reclast)

- Hypocalcemia
- Creatinine clearance < 35 mL/min and acute renal impairment
- Hypersensitivity to zoledronic acid or any components of this product

Estrogen Agonist/Antagonist (Raloxifene)

- Venous thromboembolism
- Pregnancy, women who may become pregnant, and nursing mothers

Calcitonin

- Allergy to calcitonin-salmon
- Allergy to synthetic calcitonin-salmon

Parathyroid Hormone (Teriparatide)

- Hypersensitivity to teriparatide or to any of its excipients

- Reactions have included angioedema and anaphylaxis

Denosumab (RANK Ligand Inhibitor)

- Hypocalcemia

Estrogen Prescription Drugs

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of cancer of the breast except in appropriately selected patients being treated for metastatic disease
- Known or suspected estrogen-dependent neoplasia
- Active deep vein thrombosis, pulmonary embolism or a history of these conditions
- Active or recent (within the past year) arterial thromboembolic disease (for example, stroke, myocardial infarction)
- Liver dysfunction or disease
- Known thrombophilic disorders (e.g., protein C, protein S, or antithrombin deficiency)
- Known hypersensitivity to any of the ingredients in this product
- Known or suspected pregnancy

Estrogen-Progestin Prescription Drugs

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of breast cancer
- Known or suspected estrogen-dependent neoplasia
- Active deep vein thrombosis, pulmonary embolism or a history of these conditions
- Active arterial thromboembolic disease (for example, stroke and myocardial infarction), or a history of these conditions
- Known liver dysfunction or disease
- Known thrombophilic disorders (e.g., protein C, protein S, or antithrombin deficiency)
- Known or suspected pregnancy

Qualifying Statements

Qualifying Statements

The information in this guideline is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Patient Resources

Quality Measures

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

Identifying Information and Availability

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2012 Sep. 17 p. (ACOG practice bulletin; no. 129). [78 references]

Adaptation

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

Date Released

2004 Jan (revised 2012 Sep)

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

Composition of Group That Authored the Guideline

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Jan. 14 p. (ACOG practice bulletin; no. 50). [78 references]

Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#).

Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

Patient Resources

The following are available:

- Osteoporosis: Frequently Asked Questions (FAQ048). American College of Obstetricians and Gynecologists (ACOG); 2011. Electronic copies: Available from the [American College of Obstetricians and Gynecologists \(ACOG\) Web site](#).
- Osteoporosis. Patient education pamphlet. American College of Obstetricians and Gynecologists (ACOG); 2012. Electronic copies: Available from the [ACOG Bookstore](#). Copies are also available in [Spanish](#).

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG 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 Institute on August 6, 2007. The information was verified by the guideline developer on September 10, 2007. The information was reaffirmed by the guideline developer in 2008 and updated by ECRI Institute on February 9, 2010. This summary was updated by ECRI Institute on December 10, 2010 following the U.S. Food and Drug Administration (FDA) advisory on Bisphosphonates. This summary was updated by ECRI Institute on October 10, 2012.

Copyright Statement

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

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion-criteria.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.