



Complete Summary

GUIDELINE TITLE

Bone health. In: Menopause and osteoporosis update 2009.

BIBLIOGRAPHIC SOURCE(S)

Bone health. In: Menopause and osteoporosis update 2009. J Obstet Gynaecol Can 2009 Jan;31(1 Suppl 1):S34-41. [59 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Brown JP, Fortier M, Frame H, Lalonde A, Papaioannou A, Senikas V, Yuen CK. Canadian consensus conference on osteoporosis, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S95-S112. [135 references]

COMPLETE SUMMARY CONTENT

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

SCOPE

DISEASE/CONDITION(S)

- Menopause
- Osteoporosis

GUIDELINE CATEGORY

Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide updated guidelines for health care providers on the management of menopause in asymptomatic healthy women as well as in women presenting with vasomotor symptoms or with urogenital, mood, or memory concerns, and on considerations related to cardiovascular disease, breast cancer, and bone health, including the diagnosis and clinical management of postmenopausal osteoporosis

TARGET POPULATION

Postmenopausal women at risk of or diagnosed with osteoporosis

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Assessment of risk factors for osteoporosis
2. Prediction of absolute fracture risk
3. Bone mineral density (BMD) measurement

Management/Treatment

1. Calcium and vitamin D supplementation
2. Hormone therapy
3. Selective estrogen receptor modulators (raloxifene)
4. Bisphosphonates
 - Alendronate
 - Risedronate
 - Zoledronic acid
 - Etidronate
5. Calcitonin
6. Denosumab
7. Anabolic agents
8. Parathyroid hormone (teriparatide)

9. Strontium ranelate

MAJOR OUTCOMES CONSIDERED

- Bone strength
- Bone mineral density (BMD)
- Incidence and relative risk (RR) of vertebral, non-vertebral, and hip fractures
- Side effects of therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE was searched up to October 1, 2008, and the Cochrane databases up to issue 1 of 2008 with the use of a controlled vocabulary and appropriate key words. Research-design filters for systematic reviews, randomized and controlled clinical trials, and observational studies were applied to all PubMed searches. Results were limited to publication years 2002 to 2008; there were no language restrictions. Additional information was sought in BMJ Clinical Evidence, in guidelines collections, and from the Web sites of major obstetric and gynaecologic associations worldwide.

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

Quality of Evidence Assessment*

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

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

II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.

II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

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

* Adapted from the Evaluation of Evidence criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The authors critically reviewed the evidence and developed the recommendations according to the methodology and consensus development process of the Journal of Obstetrics and Gynaecology Canada.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

- A.** There is good evidence to recommend the clinical preventive action
- B.** There is fair evidence to recommend the clinical preventive action
- C.** The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- D.** There is fair evidence to recommend against the clinical preventive action
- E.** There is good evidence to recommend against the clinical preventive action
- L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*Adapted from the Classification of Recommendations criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-E and L) and levels of evidence (I, II-1, II-2, II-3, and III) are defined at the end of the "Major Recommendations" field.

1. The goals of osteoporosis management include assessment of fracture risk and prevention of fracture and height loss. **(1B)**
2. A stable or increasing bone mineral density (BMD) reflects a response to therapy in the absence of low trauma fracture or height loss. Progressive decreases in BMD, with the magnitude of bone loss being greater than the precision error of the bone densitometer, indicate a lack of response to current therapy. Management should be reviewed and modified appropriately. **(1A)**
3. Physicians should identify the absolute fracture risk in postmenopausal women by integrating the key risk factors for fracture; namely, age, BMD, prior fracture, and glucocorticoid use. **(1B)**
4. Physicians should be aware that a prevalent vertebral or nonvertebral fragility fracture markedly increases the risk of a future fracture and confirms the diagnosis of osteoporosis irrespective of the results of the bone density assessment. **(1A)**
5. Treatment should be initiated according to the results of the 10-year absolute fracture risk assessment. **(1B)**

Calcium and Vitamin D

6. Adequate calcium and vitamin D supplementation is key to ensuring prevention of progressive bone loss. For postmenopausal women, a total intake of 1500 mg of elemental calcium from dietary and supplemental sources and supplementation with 800 IU/d of vitamin D are recommended. Calcium and vitamin D supplementation alone is insufficient to prevent fracture in those with osteoporosis; however, it is an important adjunct to pharmacologic intervention with antiresorptive and anabolic drugs. **(1B)**

Hormone Therapy

7. Usual-dosage hormone therapy (HT) should be prescribed for symptomatic postmenopausal women as the most effective therapy for menopausal

symptom relief **(1A)** and a reasonable choice for the prevention of bone loss and fracture. **(1A)**

8. Physicians may recommend low- and ultralow-dosage estrogen therapy to symptomatic women for relief of menopausal symptoms **(1A)** but should inform their patients that despite the fact that such therapy has demonstrated a beneficial effect in osteoporosis prevention **(1A)**, no data are yet available on reduction of fracture risk.

Bisphosphonates

9. Treatment with alendronate, risedronate, or zoledronic acid should be considered to decrease the risk of vertebral, nonvertebral, and hip fractures. **(1A)**
10. Etidronate is a weak antiresorptive agent and may be effective in decreasing the risk of vertebral fracture in those at high risk. **(1B)**

Selective Estrogen Receptor Modulators

11. Treatment with raloxifene should be considered to decrease the risk of vertebral fractures. **(1A)**

Calcitonin

12. Treatment with calcitonin can be considered to decrease the risk of vertebral fractures and to reduce pain associated with acute vertebral fractures. **(1B)**

Parathyroid Hormone

13. Treatment with teriparatide should be considered to decrease the risk of vertebral and nonvertebral fractures in postmenopausal women with severe osteoporosis. **(1A)**

Definitions:

Quality of Evidence Assessment*

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

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

II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.

II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

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*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.***

Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.*

***Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

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").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention, risk assessment, and management of osteoporosis in postmenopausal women

POTENTIAL HARMS

- The most common side effects of oral bisphosphonate therapy are abdominal pain and dysphagia. However, in the randomized controlled trials (RCTs) conducted to date, the incidence rates of upper gastrointestinal side effects of

- both alendronate and risedronate have been comparable to those of placebo. Recently, reports of mandibular or maxillary osteonecrosis as a rare complication of bisphosphonate use have been published.
- Teriparatide is well tolerated, with only minor adverse events such as nausea, headaches, and transient mild hypercalcemia.
 - Side effects associated with strontium ranelate have been limited to nausea and diarrhea during the first few months of therapy

QUALIFYING STATEMENTS

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This guideline reflects emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2006 Feb (revised 2009 Jan)

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following conflicts of interest have been disclosed by the authors.

Dr Reid: Speaker or consultant to Wyeth, Bayer, Organon, Proctor and Gamble, Novo Nordisk; advisory boards: Paladin, Wyeth; research support: Organon, Bayer.

Dr Blake: Speaker or consultant to Wyeth, Merck, Glaxo Smith Kline, Bayer; advisory boards: Bayer, Wyeth and Lilly, Novo Nordisk.

Dr Abramson: Speaker or consultant to Abbott, Astra Zeneca, Boehringer Ingelheim, Bristol Myer Squibb, Dupont, Eli Lilly, Lifespeak, Novartis, Fournier, Merck Frosst, Pfizer, Servier, Schering, Sanofi-Aventis; advisory boards: Astra Zeneca, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis; research support: Astra Zeneca, Boehringer Ingelheim, Merck.

Dr Khan: Speaker or consultant to Amgen, Merck, Lilly, Novartis, Servier, Proctor and Gamble; research support: Merck, Lilly, Novartis, Alliance for Better Bone Health.

Dr Senikas: None declared.

Dr Fortier: Speaker or consultant to Proctor and Gamble, Merck; advisory boards: Amgen, Bayer, Novo Nordisk, Novartis, GlaxoSmith Kline, Lilly, Paladin; research support: Wyeth, Sanofi.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Society of Obstetricians and Gynaecologists of Canada Web site](#).

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 4, 2009. The information was verified by the guideline developer on May 21, 2009.

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