YELLOW

Guideline: 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada

Developer: Scientific Advisory Council of Osteoporosis Canada

Summary: This is a high-quality guideline, but the CTFPHC has identified some concerns that may limit its applicability. In particular, the CTFPHC identified some reservations about the methods used, which should be considered if the recommendations are applied, especially those recommendations with lower levels of evidence and certainty.

OVERVIEW This guideline[1] focuses on the prevention of fragility fractures in adults, an issue that is clinically important and poses a significant health burden in Canada. Among women, the annual incidence of osteoporotic fracture is more than twice that of heart attack, stroke and breast cancer combined[2]. Primary care physicians play a major role in prevention of these fractures; however, there are wide variations in practice, including underuse of potentially beneficial treatments. The guideline was developed in Canada by a team with diverse expertise. It addresses prevention strategies such as screening for fragility fracture risk and pharmacologic therapy.

RELEVANCE TO CTFPHC MANDATE All sections of this guideline are applicable to the CTFPHC mandate of prevention in primary care.

POPULATION The reviews focused on women and men over the age of 50 years. Therefore, these guidelines do not apply to children and younger adults.

EVIDENCE REVIEW METHODS: Two reviews were conducted to support the guideline[2]. A *de novo* search for risk assessment models identified 26 studies published from 1990 to December 2009. The review for pharmacologic therapies and adverse events was an update of the systematic review conducted by MacLean *et al*.[3]; it identified 34 studies published from January 2007 to December 11, 2009. The MEDLINE, Embase and EBM Reviews databases were searched. Searches were updated before publication, and relevant data to September 19, 2010, were included.

GRADING SYSTEM: Recommendations were assigned grades of A to D on the basis of study design and expert consensus, with Grade A being the highest level of evidence (e.g., systematic reviews, randomized controlled trials) and Grade D being the lowest level of evidence (e.g., case series, case reports, case–control studies)[4]. A detailed summary of the grading scheme can be found at: http://www.cmaj.ca/content/suppl/2002/04/08/159.8.DC1/cpg98eng.pdf.

COMMENTARY: These recommendations address the assessment, prevention and management of people over the age of 50 years who are at risk of fragility fractures. The accompanying evidence synthesis provides a comprehensive summary of the current literature on osteoporosis screening and fragility fractures.

The CTFPHC identified some concerns during its appraisal. The competing interests of the guideline developers are listed, but how these were handled during guideline production is not described. Although Appendix 1 of the guideline describes the methods used for the evidence synthesis[2], neither the specific research questions that the review addressed nor the target audience for the guideline are well described. It is unclear why only 17 of the 26 full-text articles identified during the review of methods for risk assessment were used to support the recommendations. The details of the grading system are provided in Appendix 1 but not in the guideline itself, which could make interpretation and application of the recommendations difficult. For most therapeutic (pharmacologic) interventions, there are good links between the evidence and the recommendations, but the links are less clear for recommendations on exercise, calcium and vitamin D. Recommendations on the ages to start and stop screening do not appear to be supported by the evidence. Finally, although consideration of patient preferences is briefly mentioned, the guideline would be stronger if it explicitly stated what factors should be considered in such assessment.

The CTFPHC recognizes the importance of osteoporosis and resulting fractures. However, given the CTFPHC's reservations about the methods used, this guideline may be used but caution should be exercised in its application, especially for recommendations with lower levels of evidence and certainty.

CTFPHC APPRAISAL COLOUR LEGEND

GREEN

This is a high-quality guideline that can be used to guide preventive care in Canada.

YELLOW

This is a high-quality guideline, but the CTFPHC has identified some concerns that may limit its applicability.

RED

This is a high-quality guideline, but the CTFPHC does not recommend its use in Canada.

Recommendations: Scientific Advisory Council of Osteoporosis Canada

The recommendations and the full guideline can be found at: http://www.cmaj.ca/content/early/2010/10/12/cmaj.100771.full.pdf+html?ijkey=edc6c6048e7d4acdc41368fe3f1e622bf5a2deac&keytype2=tf_ipsecsha

WHO SHOULD I ASSESS FOR OSTEOPOROSIS AND FRACTURE RISK?

1. Individuals over age 50 who have experienced a fragility fracture should be assessed [Grade A].

HOW DO I ASSESS FOR OSTEOPOROSIS AND FRACTURE RISK?

1. Measure height annually, and assess for the presence of vertebral fractures [Grade A].
2. Assess history of falls in the past year. If there has been such a fall, a multifactorial risk assessment should be conducted, including the ability to get out of a chair without using arms [Grade A].

WHAT INVESTIGATIONS SHOULD I ORDER INITIALLY?

1. Perform additional biochemical testing to rule out secondary causes of osteoporosis in selected patients, on the basis of the clinical assessment [Grade D].
2. Measure serum level of 25-hydroxyvitamin D in individuals who will receive pharmacologic therapy for osteoporosis, those who have sustained recurrent fractures or have bone loss despite osteoporosis treatment, and those with comorbid conditions that affect absorption or action of vitamin D [Grade D].
3. Serum 25-hydroxyvitamin D should be measured after three to four months of adequate supplementation and should not be repeated if an optimal level (≥75 nmol/L) is achieved [Grade B].
4. Serum 25-hydroxyvitamin D should not be measured in healthy adults at low risk of vitamin D deficiency, i.e., without osteoporosis or conditions affecting the absorption of action of vitamin D [Grade D].

ASSESSMENT OF FRACTURE BY RADIOGRAPHY OR DUAL-ENERGY X-RAY ABSORPTIOMETRY

1. Perform lateral thoracic and lumbar spine radiography or vertebral fracture assessment by dual-energy x-ray absorptiometry if clinical evidence is suggestive of a vertebral fracture [Grade A].

HOW DO I ASSESS 10-YEAR FRACTURE RISK?

1. Assessment of the absolute risk of fracture should be based on established factors, including age, bone mineral density, prior fragility fractures and glucocorticoid use [Grade A].
2. The 2010 version of the Canadian Association of Radiologists and Osteoporosis Canada tool and the Canadian version of the WHO Fracture Risk Assessment tool should be used in Canada, because they have been validated in the Canadian population [Grade A].
3. For purposes of reporting bone mineral density, the 2010 version of the Canadian Association of Radiologists and Osteoporosis Canada tool is currently the preferred national risk assessment system [Grade D].
4. Only the T-score for the femoral neck (derived from the reference range for white women of the National Health and Nutrition Education Survey III) should be used to calculate risk of future osteoporotic fractures under either system [Grade D].
5. Individuals with a T-score for the lumbar spine or total hip ≤ –2.5 should be considered to have at least moderate risk [Grade D].
6. Multiple fractures confer greater risk than a single fracture. In addition, prior fractures of the hip and vertebra carry greater risk than fractures at other sites [Grade B].

WHAT ARE THE THERAPEUTIC OPTIONS?

Exercise and prevention of falls

1. Exercises involving resistance training appropriate for the individual's age and functional capacity and/or weight-bearing aerobic exercises are recommended for those with osteoporosis or at risk for osteoporosis [Grade B].
2. Exercises to enhance core stability and thus to compensate for weakness or postural abnormalities are recommended for individuals who have had vertebral fractures [Grade B].
3. Exercises that focus on balance, such as tai chi, or on balance and gait training should be considered for those at risk of falls [Grade A].
4. Use of hip protectors should be considered for older adults residing in long-term care facilities who are at high risk for fracture [Grade B].

Calcium and vitamin D

1. The total daily intake of elemental calcium (through diet and supplements) for individuals over age 50 should be 1200 mg [Grade B].
2. For healthy adults at low risk of vitamin D deficiency, routine supplementation with 400–1000 IU (10–25 μg) vitamin D_3 daily is recommended [Grade D].
3. For adults over age 50 at moderate risk of vitamin D deficiency, supplementation with 800–1000 IU (20–25 μg) vitamin D_3 daily is recommended. To achieve optimal vitamin D status, daily supplementation with more than 1000 IU (25 μg) may be required. Daily doses up to 2000 IU (50 μg) are safe and do not necessitate monitoring [Grade C].
4. For individuals receiving pharmacologic therapy for osteoporosis, measurement of serum 25-hydroxyvitamin D should follow three to four months of adequate supplementation and should not be repeated if an optimal level (≥ 75 nmol/L) is achieved [Grade D].

PHARMACOLOGIC THERAPY

1. For menopausal women requiring treatment of osteoporosis, alendronate, risedronate, zoledronic acid and denosumab can be used as first-line therapies for prevention of hip, nonvertebral and vertebral fractures [Grade A].
2. For menopausal women requiring treatment of osteoporosis, raloxifene can be used as a first-line therapy for prevention of vertebral fractures [Grade A].
3. For menopausal women requiring treatment of osteoporosis in combination with treatment for vasomotor symptoms, hormone therapy can be used as first-line therapy for prevention of hip, nonvertebral and vertebral fractures [Grade A].
4. For menopausal women intolerant of first-line therapies, calcitonin or etidronate can be considered for prevention of vertebral fractures [Grade B].
5. For men requiring treatment of osteoporsis, alendronate, risedronate and zoledronic acid can be used as first-line therapies for prevention of fractures [Grade D].
6. Testosterone is not recommended for the treatment of osteoporosis in men [Grade B].

ADVERSE EFFECTS

1. The potential benefits and risks of the prescribed agents should be discussed before therapy is initiated, to support informed decision-making [Grade D].

SPECIAL GROUPS

1. For individuals over age 50 who are on long-term glucocorticoid therapy (≥ three months cumulative therapy during the preceding year at a prednisone-equivalent dose ≥ 7.5 mg daily), a bisphosphonate (alendronate, risedronate, zoledronic acid) should be initiated at the outset and should be continued for at least the duration of the glucocorticoid therapy [Grade A].
2. Teriparatide should be considered for those at high risk for fracture who are taking glucocorticoids (≥ three months cumulative therapy during the preceding year at a prednisone-equivalent dose ≥ 7.5 mg daily) [Grade A].
3. For long-term glucocorticoid users who are intolerant of first-line therapies, calcitonin or etidronate may be considered for preventing loss of bone mineral density [Grade B].
4. Women who are taking aromatase inhibitors and men who are undergoing androgen-deprivation therapy should be assessed for fracture risk, and osteoporosis therapy to prevent fractures should be considered [Grade B]

HOW SHOULD I MANAGE PATIENTS AT RISK OF FRACTURE?

1. Initiation of pharmacologic treatment for osteoporosis should be predicated on an assessment of absolute fracture risk by means of a validated fracture prediction tool [Grade D].

High risk

1. Pharmacologic therapy should be offered to patients at high absolute risk (> 20% probability for major osteoporotic fracture over 10 years) [Grade D].
2. Individuals over age 50 who have had a fragility fracture of the hip or vertebra and those who have had more than one fragility fracture are at high risk for future fractures, and such individuals should be offered pharmacologic therapy [Grade B].

Moderate risk

1. For those at moderate risk of fracture, patient preference and additional risk factors (Appendix 1, available at www.cmaj.ca/cgi/content/full/cmaj.100771/DC1) should be used to guide pharmacologic therapy [Grade C].

Low risk

1. For patients with a low risk of fracture, pharmacologic therapy is not usually required.

WHEN SHOULD I STOP OR USE COMBINATION THERAPY?

1. Individuals at high risk for fracture should continue osteoporosis therapy without a drug holiday [Grade D].
2. Clinicians should avoid simultaneously prescribing more than one antiresorptive agent for fracture reduction [Grade D].

KNOWLEDGE TRANSLATION

1. Following a fragility fracture, an educational initiative should be targeted at both the patient and the primary care physician [Grade B].
2. Case management is recommended as an effective approach to postfracture care, to improve both the diagnosis and the management of osteoporosis [Grade A].
3. Point-of-care tools and other targeted strategies are recommended to support the implementation of osteoporosis guidelines in clinical practice [Grade B].

REFERENCES

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2. Papaioannou A, Morin S, Cheung AM, Atkinson S, Brown JP, Feldman S et al.; Scientific Advisory Council of Osteoporosis Canada. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. Appendix 1: Background materials for 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ*. 2010;182(17):1864-1873. Available at: http://www.cmaj.ca/content/suppl/2010/10/12/cmaj.100771.DC1/App_1_Jul_14_2011.doc.pdf. Accessed 2013 Nov 13.
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4. Meltzer S, Leiter L, Daneman D, Gerstein HC, Lau D, Ludwig S, et al. 1998 clinical practice guidelines for the management of diabetes in Canada. *CMAJ*. 1998;159 Suppl 8:S1-S29.