

RxFiles Potpourri of Q&As
Osteoporosis, Vitamin D, SMBG & Anti-infectives
Oct 2010

OSTEOPOROSIS (OP)

Should consideration be given to a “drug holiday” for patients on a bisphosphonate?

♦ Recent concerns about long-term treatment have raised the proposition of whether a “drug holiday” should be considered for bisphosphonate patients.1,2,3
(See SDIS Bisphosphonate Safety& the RxFiles OP Treatment Chart5 pg 72-73)

♦ Rather than consider a drug holiday, one should consider the patient’s overall fracture risk and whether a bisphosphonate is actually indicated.
  o For patients with high fracture risk, benefit is generally considered to outweigh the possible risks of long term therapy which are rare (e.g. osteonecrosis of the jaw6, atypical fractures7, atrial fibrillation8 and esophageal cancer9).
  o For patients with low fracture risk, discontinuation of bisphosphonate therapy should be considered.
  o Some low/moderate risk patients may be unnecessarily receiving bisphosphonates due to the shift in guidelines to consider overall fracture risk10,11 rather than just bone mineral density (BMD).12

♦ Tools are available to estimate overall fracture risk:
  o BMD lab reports that include a 10 year fracture risk
  o Graphical estimate (data strongest for women)13
  o FRAX risk assessment (Canadian Data Set - available)14

♦ Special consideration should be given to higher risk if:
  o fragility fracture history after age 40
  o corticosteroid use (>3 months with ≥2.5mg prednisone/day)
  o smoking
  o family history of osteoporotic fracture, especially hip

How can we improve adherence to bisphosphonates therapy when indicated in high risk patients?

♦ A Quebec cohort study found that 52% of women over age 70 years had discontinued therapy after 12 months.15

♦ To increase adherence consider the following:
  o cost issues (see table 1)
  o less frequent dosing. (Weekly regimens may be associated with less discontinuation than daily.16)

Table 1: Bisphosphonate – OP Regimens & Cost/Year

<table>
<thead>
<tr>
<th>Bisphosphonate</th>
<th>Dose</th>
<th>Frequency</th>
<th>Cost/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate</td>
<td>10mg</td>
<td>Po daily</td>
<td>$520</td>
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<tr>
<td>Alendronate</td>
<td>70mg</td>
<td>Po once weekly</td>
<td>$400</td>
</tr>
<tr>
<td>Alendronate</td>
<td>70mg</td>
<td>Po once weekly</td>
<td>$710</td>
</tr>
<tr>
<td>Alendronate/Cholecalciferol</td>
<td>70mg/5600 IU</td>
<td>Po weekly</td>
<td>$360</td>
</tr>
<tr>
<td>Risedronate</td>
<td>35mg</td>
<td>Po once monthly</td>
<td>$360</td>
</tr>
<tr>
<td>Risedronate</td>
<td>150mg</td>
<td>Po monthly</td>
<td>$840</td>
</tr>
<tr>
<td>Zoledronic acid</td>
<td>5mg</td>
<td>IV yearly</td>
<td>$740</td>
</tr>
</tbody>
</table>

Note: Etidronate PO/POCIAL low cost ($160/year) but lacks hip fracture evidence.

What dose of Vitamin D is recommended in OP?

♦ There has been a lot of discussion about the prevalence of Vitamin D deficiency and claims for benefit of supplementation.

♦ There is evidence for the safety and efficacy of daily maintenance doses in the range of 800-2,000 IUs (international units) of vitamin D in those age >50.17 Specific dose recommendations will vary depending on age, season, etc. (See Vitamin D Claims - Q&A 18)

♦ An initial loading dose is sometimes used if serum 25-OHD levels are less than 25-50 nmol/L. (Generally, only recommend levels if there is a high risk of deficiency or toxicity concern.) Not routinely: 17,19

What is the status of calcium given the recent concern about a possible association with MI?

♦ A recent meta-analysis of randomized controlled trials (RCTs) found that persons taking calcium supplements without vitamin D had an increased risk of MI.20 The meta-analysis had limitations which have been discussed elsewhere.21 (Based on patient level data, from 5 studies of over 8,000 patients, the number needed to harm (NNH) was 69; e.g. for every 69 patients treated with calcium 500mg or more for 5 years (without vitamin D), there was one extra MI.)

♦ Current take home messages for most patients:
  o Avoid exceeding the maximum daily 1,500mg intake for combined pills and diet (1,200mg elemental calcium for menopausal women and men >50yrs)
  o Since patients typically get 300-800mg or more in their diet, this means that a supplement providing 500 – 1000mg of elemental calcium is enough for most, and some may not require any.
  o See Calcium Calculator tool(s) online 22,23

  o Ensure adequate Vitamin D intake and avoid excess calcium!

Highlights

1) When deciding whether to treat osteoporosis (OP), assess fracture risk rather than BMD alone.

2) The benefit of bisphosphonates is generally considered to outweigh harms in OP patients who are truly “high risk”. However, patients at low/moderate risk of fracture may be receiving bisphosphonates unnecessarily, and the safety concerns may outweigh any benefit.

3) Ensure adequate vitamin D (e.g. 800 – 2,000 IU) for most OP patients, but avoid excessive calcium! Bone care/hygiene for all: ↓ falls/alcohol/smoking, ↑ exercise.
Self Monitoring of Blood Glucose (SMBG)

How useful is SMBG for non-insulin patients with T2DM?

- The value of routine ongoing SMBG, especially in most patients not on insulin, has come into question, due to uncertain or marginal benefits & significant cost. A possible association with depression & lower quality of life has been noted.
- When considering whether to & how often to test, ask, “Will the test result in a positive behaviour change?”
- For more information, see RxFiles SMBG Chart and the comparison of COMPUS and CDA recommendations relating to SMBG. [It is estimated that > $150million/year could be saved with more targeted SMBG without adversely affecting health outcomes.]

Influenza Immunization Update – Fall 2010

- The Fall 2010 vaccine will cover three strains:
  - A/California/07/2009 (H1N1) pandemic strain from 2009
  - A/Perth/16/2009 (H3N2)
  - B/Brisbane/60/2008
- Vaccine will be non-adjuvanted.
- Vaccine is recommended for everyone age ≥6months without contraindications. (Coverage will again be universal in SK.)
- Efforts should ensure that those at higher risk are especially encouraged to get the vaccine.

Viral Infections

- Remember the many infections for which the initial cause is predominantly viral:
  - Pharyngitis, especially in adults
  - Acute bronchitis < 10days
  - Acute sinusitis < 10days
- Antibiotics are often not necessary! If treating with antibiotics, consider an agent with a narrow but suitable spectrum; treat only for time indicated.

Acute Otitis Media (AOM)

- Watchful waiting has been recognized as a valuable strategy to reduce antibiotic overuse in some otherwise healthy children, >2yr of age. (It may be appropriate for children 6 months to 2 years when appropriate medical follow-up at 24 hours can be assured.)
  - X5 days in age >2yr (including adults)
  - X10 days in age <2yr
- Amoxicillin is still often the drug of choice, but high dose (~80mg/kg/day) is often recommended in AOM to cover intermediate resistant Streptococcus pneumonia. (To achieve high dose amoxicillin with amoxicillin/clavulanic acid, may give amoxicillin 40mg/kg in addition to amox/clav 40mg/kg per day.)
- Amoxicillin may be given q12h (usual max 3-4g/day);
- These doses are relatively high even by adult standards. [See: RxFiles Anti-infective Common Infections Chart pg 54-55]

Cephalexin (Keflex): when and when not to use

- Cephalexin is useful for skin infections caused by methicillin sensitive S. aureus or streptococci.
- It should not commonly be used for respiratory infections as it does not cover usual pathogens. Limiting use will help preserve effectiveness for skin infections.

Deferred prescriptions

- A deferred prescription (e.g. provisional “wait and see”) may be useful in some cases, where patient can be instructed to fill “only if...”

Trends in Anti-infective Therapy

- Macrolide resistance has increasing (Penicillin Resistant Strep Pneumococcus: ~20% are macrolide resistant)
- To minimize antibiotic pressure and emerging resistance, ensure adequate dose for shortest effective period of time. (Hit hard & short!)


References available online at www.RxFiles.ca
<table>
<thead>
<tr>
<th>Bisphosphonates</th>
<th>Common</th>
<th>NNT or CI</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Acetate</strong></td>
<td>GI SE: (abdominal pain, diarrhea, dyspepsia, flatulence, nausea, headache)</td>
<td>91</td>
<td></td>
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<tr>
<td><strong>Actetate</strong></td>
<td>GI SE: (abdominal pain, diarrhea, dyspepsia, flatulence, gastritis, vomiting, anemia, headache, pruritus, rash)</td>
<td>91 or 20</td>
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<tr>
<td><strong>Alendronate</strong></td>
<td>Post-dose sx: fever, myalgia, headache</td>
<td>91 for 3 yrs in</td>
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<td><strong>Clodronate</strong></td>
<td>Common: Acetald cystitis, breast cancer</td>
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<tr>
<td><strong>Evista</strong></td>
<td>Common: GI SE: (diarrhea, dyspepsia, flatulence, nausea, dizziness, headache)</td>
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<tr>
<td><strong>Etidronate</strong></td>
<td>NNT = 20 for 3 yrs in</td>
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<tr>
<td><strong>Fosamat</strong></td>
<td>Common: GI SE: (abdominal pain, diarrhea, dyspepsia, flatulence, nausea, headache)</td>
<td>91 for 3 yrs in</td>
<td></td>
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<tr>
<td><strong>Risedronate</strong></td>
<td>Common: Acetald cystitis, breast cancer</td>
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<tr>
<td><strong>Teriparatide</strong></td>
<td><strong>Serious:</strong> (rare): epistaxis 2.4 vs 2%, nasal discomfort 1.6 vs 1%, sinusitis 1.6 vs 0.5%, flu-like symptoms *</td>
<td>27</td>
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<tr>
<td><strong>Zoledronic Acid</strong></td>
<td>NNT = 20 for 3 yrs in</td>
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<tr>
<td><strong>Calcitonin</strong></td>
<td>Calcitonin considered to</td>
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<tr>
<td><strong>Calcitonin</strong></td>
<td>Common: vs: placebo</td>
<td>27</td>
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</table>
Calcium, g

Oval, chew, dissolvable tablet; liquid NIHb covers v. Calcium 500mg, Calcium 500 + Vit D 1250iU, Calcium 500 + Vit D 4000iU w/thorium dioxide or niobium NIHb

Sandoz, Gramcal, Calcan, Os-cal 250mg, Calcium Ca content; carbonate 40% citrate 21%

Vit D 4=calcichoral, g 4= 400, 100, 0.5/0.0325 tab; oral, compr with Ca++

Vit D3=ergocalciferol 50.000 iU/cap liquid (0.5/75.000 mg cap made from powder (calcitriol: hypercalcemia risk, ↑cost)

Common: Constipation, bloating
Serious: Renal stone [HR = 1.17, 95% CI 1.02 to 1.34] 33 yrs; but unexpectedly no correlation with total calcium intake & kidney stone formation

Adverse effect of total calcium intake in excess of >2g/day may include high blood levels calcium, renal function & renal calculus formation (♂, ? M Romanofsky T Risk HR=1.27, 95% CI 1.01-1.58) No records of cases calcium intoxication from food.

Ca + Vit D: RR=0.84, 95% CI 0.73-0.96

NNT=45 for 2-yr or without a previous vertebral fracture 15" Men-avg yrs

High 500 IU/day for 10yr

Calcium & Vit D supplementation alone insufficient to prevent # in those with OP, but critical adjunct with antiresorptive & anabolic OP meds
Consuming >500mg calcium elements at one time maximizes absorption. 5

NIHB covers:
• Calcium 500 + Vit D 1250iU, 300iU, 200iU
• Calcium 500 + Vit D 4000iU, 360iU, 240iU
• Calcium 500 + Vit D 5000iU, 540iU, 360iU

Vit D alone or low dose likely does not prevent hip, vertebral, or any new # 37
• Some recommend 2,000iU in winter months & 1,000iU in summer. 38

Consider single Vit D loading dose if severely deficient (eg. 75-150,000 IU)

Vit D sources: dairy products, salmon, sardines & tuna. Sunscreens ↓Vit D. Sun exposure ↑on arm/leg, between 10am-3pm in summer often adequate.

Vitamin D3 (Calciflexin) D3 50,000 iU: If <50 yrs: 400-1000 iU(10-20iU/kg/day) for 6-12months; ≥50 yrs: 800-1200 iU/day

Calcium & Vitamin D3 (Calciflexin) supplementation is preferred over Vit D2 with medroxyprogesterone WHI:

NNT = 385 for 5 yrs in women with or without a previous fracture 45

Calcium & Vitamin D3 (Calciflexin) supplementation is preferred over Vit D2 with medroxyprogesterone WHI:

HT for symptomatic postmenopausal 25 as the most effective tx for menopausal Sx relief, vaginal atrophy & the prevention of bone loss / .

Consider low conjugated estrogen 0.2mg or micronized estradiol 0.5mg & ultrawave ↓to the low dose, if both prevent OP & OP symptoms menopause. Inform that it works for some preventing OP, but limited data on ↓to the risk.

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Table: Ten-year absolute fracture risk for women (CAROC basal risk 2010)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Low Risk &lt;10%</th>
<th>Moderate Risk 10% - 20%</th>
<th>High Risk &gt;20%</th>
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<tbody>
<tr>
<td></td>
<td>Femoral neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>&gt; -2.5</td>
<td>-2.5 to -3.8</td>
<td>&lt;-3.8</td>
</tr>
<tr>
<td>55</td>
<td>&gt; -2.5</td>
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<td>&lt;-3.8</td>
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<tr>
<td>60</td>
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<td>-2.3 to -3.7</td>
<td>&lt;-3.7</td>
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<td>70</td>
<td>&gt; -1.9</td>
<td>-1.9 to -3.5</td>
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<td>80</td>
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<td>-1.2 to -2.9</td>
<td>&lt;-2.9</td>
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<td>85</td>
<td>&gt; -0.5</td>
<td>-0.5 to -2.6</td>
<td>&lt;-2.6</td>
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<tr>
<td>90</td>
<td>&gt; -0.1</td>
<td>-0.1 to -2.2</td>
<td>&lt;-2.2</td>
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</table>

Table 3: Ten-year absolute fracture risk for men (CAROC basal risk 2010)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Low Risk &lt;10%</th>
<th>Moderate Risk 10% - 20%</th>
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<td>-2.0 to -3.8</td>
<td>&lt;-3.8</td>
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</table>

There are two risk assessment tools currently available and recommended in the 2010 Canadian OP Guidelines:

1) CAROC Charts/Graphs
   (as per tables at left & graphs on previous page)
   ✐ requires BMD

2) FRAX Canada – Online Calculator
   ✐ can be used with OR without a BMD
   [http://www.sheffield.ac.uk/FRAX/tool.jsp?country=19]

Updated 2010, but tables initially in Can Assoc Radiol J 56, Siminoski K et al, Recommendations for Bone Mineral Density Testing in Canada, p. 178-188, Copyright Canadian Association of Radiologists 2005
References: Osteoporosis Treatment Chart

1 E-cps, accessed online Jan 11, 2010


Black, Dennis M., Kelly, Michael P., Genant, Harry K., et al. the Fracture Intervention Trial (FIT, FLEX) and HORIZON Pivotal Fracture Trial Steering Committees, Bisphosphonates and Fractures of the Subtrochanteric or Diaphyseal Femur. N Engl J Med 2010 0: NEJMoa1001086. (N=12 fractures were subtrochanteric or diaphyseal femur in 14,195 women; a rate of 2.3 per 10,000 pt-yrs).


Cardwell CR.; Abnet CC.; Cantwell MM.; et al. Exposure to Oral Bisphosphonates and Risk of Esophageal Cancer. JAMA. 2010;304(6):657-663.

Green J, Czanner G, Reeves G, Watson J, Wise L, Beral V. Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort. BMJ. 2010 Sep 1;341:c4444. doi:10.1136/bmj.c4444. The risk of oesophageal cancer increased with 10 or more prescriptions for oral bisphosphonates and with prescriptions over about a five year period. In Europe and North America, the incidence of oesophageal cancer at age 60-79 is typically 1 per 1000 population over five years, and this is estimated to increase to about 2 per 1000 with five years' use of oral bisphosphonates.


Avenell a, Gillespie WJ, Gillespie LD et al. Vitamin D and vitamin D analogues for preventing fractures associated with involutional and post-menopausal osteoporosis. Cochrane Database of Systematic Reviews. (2):CD000227, 2009


Additional articles:


DIPART (Vitamin D Individual Patient Analysis of Randomized Trials) Group. Patient level pooled analysis of 68 500 patients from seven major vitamin D fracture trials in US and Europe. BMI. 2010 Jan 12;340:b5463. doi:10.1136/bmj.b5463. This individual patient data analysis indicates that vitamin D given alone in doses of 10-20 microg is not effective in preventing fractures. By contrast, calcium and vitamin D given together reduce hip fractures and total fractures, and probably vertebral fractures, irrespective of age, sex, or previous fractures.


FDA Oct/10 Atypical subtrochanteric femur fractures are fractures in the bone just below the hip joint. Diaphyseal femur fractures occur in the long part of the thigh bone. These fractures are very uncommon and appear to account for less than 1% of all hip and femur fractures overall. Although it is not clear if bisphosphonates are the cause, these unusual femur fractures have been predominantly reported in patients taking bisphosphonates.


Hanley DA, Cranney A, Jones G, et al. Vitamin D in adult health & disease: a review and guideline statement from Osteoporosis Canada—summary.CMAJ 2010 0: cmaj.091062. Health Canada Oct/10 & Novartis, is notifying healthcare professionals and the public of reports of renal impairment and renal failure requiring dialysis or with fatal outcome that occurred in patients with history of renal impairment or other risk factors receiving CLASTRA (zolendronic acid).


International Society for Clinical Densitometry http://www.iscd.org/


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Kirby MW and Spritzer C. Radiographic detection of hip and pelvic fractures in the emergency department. AJR Am J Roentgenol 2010 Apr; 194:1054.

Klazen CA, Lohle PN, de Vries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised


Lim LS, Hoeksema LJ, Sherin K; ACPM Prevention Practice Committee. Screening for osteoporosis in the adult U.S. population: ACPM position statement on preventive practice. Am J Prev Med. 2009 Apr;36(4):366-75. All adult patients aged >or=50 years should be evaluated for risk factors for osteoporosis. Screening with BMD testing for osteoporosis is recommended in women aged >or=65 years and in men aged >or=70 years. Younger postmenopausal women and men aged 50-69 years should undergo screening if they have at least one major or two minor risk factors for osteoporosis. It is also recommended that clinicians consider using an osteoporosis risk-assessment tool to evaluate absolute fracture risk to determine appropriate osteoporosis therapies.


National Osteoporosis Foundation (NOF) http://www.nof.org/


QFractureScore http://www.qfracture.org/


Sanders Kerrie M.; Stuart Amanda L.; Williamson Elizabeth J.; et al. Annual High-Dose Oral Vitamin D (500,000IU x 1yr for 3-5yrs: increased falls & fractures) and Falls and Fractures in Older Women: A Randomized Controlled Trial. JAMA. 2010;303(18):1815-1822.


Sontag A, Krge JH. First fractures among postmenopausal women with osteoporosis. (MORE) J Bone Miner Metab. 2010 Jan 7. (Spine & radius fractures)


Bisphosphonates have demonstrated antifracture efficacy in randomized, placebo-controlled trials of 3 and 4 yr duration and have been widely used since the initial release of alendronate in 1995. For zoledronic acid and risedronate, an early effect (fractures reduced within 6-12 months of starting therapy) has been shown. A sustained effect for risedronate has been shown through 5 yr and suggested through 7 yr. Ten-year data with alendronate and 8 yr data with risedronate indicated good tolerability and safety; it is unlikely that longer-term studies will be done.


Winzenberg TM, Powell S, Shaw KA, Jones G. Vitamin D supplementation for improving bone mineral density in children. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD006944. DOI: 10.1002/14651858.CD006944.pub2. These results do not support vitamin D supplementation to improve bone density in healthy children with normal vitamin D levels, but suggest that supplementation of deficient children may be clinically useful.


Web Links:

National Osteoporosis Foundation (NOF) [http://www.nof.org/](http://www.nof.org/)

Osteoporosis Canada – [www.osteoporosis.ca](http://www.osteoporosis.ca)

QFractureScore [http://www.qfracture.org/](http://www.qfracture.org/)

Simple Calculated Osteoporosis Risk Estimation (SCORE) tool [http://osteoed.org/tools.php](http://osteoed.org/tools.php) (sensitivity 91%, specificity 40%)