Post-Menopausal Osteoporosis

Chaim Vanek, MD (vanekc@ohsu.edu)

Associate Professor, OHSU

Endocrinology; Bone and Mineral Unit

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Diagnosis of Osteoporosis

- 1) Clinical Judgment: Fragility fractures, general frailty
- 2) Bone density
  - T-score less than -2.5 at spine, total hip, or femoral neck of hip
    - Trabecular bone score complements DXA report not a substitute
- 3) Fracture Risk Assessment Tool (FRAX) – Use when no clear osteoporosis present on bone density (Google FRAX, free calculator)

  - 20.0 % or greater 10-year risk of any osteoporotic fracture

  OR

  - 3.0 % or greater 10-year risk of hip fracture

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Calculation Tool FRAX

Please answer the questions below to calculate the ten-year probability of fracture with or without BMD.

Continent: North America

Country: US (Caucasian)

Local Reference: Reference (optional)

Use US (Caucasian) for all Ethnicities

About the risk factors ?

Individuals with fracture risk assessed since 1st June 2011 : 11,656,079

Questionnaire

1. Age (between 40 and 90 years): 63
2. Sex: Female (selected) / Male
3. Weight: Pounds 123 (Pounds / Inch...)
4. Height: Inches 61.5
5. Previous Fracture: ✓
6. Parent Fractured Hip: X

7. Current smoking: X
8. Glucocorticoids: X
9. Rheumatoid arthritis: X
10. Secondary osteoporosis: X
11. Alcohol 3 or more units/day: X
12. Femoral neck BMD: T-score -1.8

Calculate | Clear

Age : 63 BMI : 22.9 with BMD

THE TEN-YEAR PROBABILITY OF FRACTURE

Major osteoporotic	15 %
Hip Fracture	2.0 %

Adjust your results, try FRAXplus®

What does FRAXplus® do ? Click here

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Calculate | Clear

Age : 63 BMI : 22.9 with BMD

THE TEN-YEAR PROBABILITY OF FRACTURE

Major osteoporotic	28 %
Hip Fracture	2.1 %

Adjust your results, try FRAXplus®

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FRAX Clinical Pearl

- FRAX most useful in patients with osteopenia on bone density
  - T-score of -1.0 to -2.4 at spine, total hip, or femoral neck of hip
- Identifies patients with osteoporosis based on fracture risk
  - Parental history of hip fracture important data point
- Provides assurance that fracture risk is not elevated
  - Avoids over treatment
- Always calculate using the ‘Caucasian’ setting as FRAX underestimates fracture risk in Blacks, Asians, and Hispanics
- 20.0 % or greater 10-year risk of any osteoporotic fracture OR
- 3.0 % or greater 10-year risk of hip fracture

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Osteoporosis Workup

- Highly Recommended
  - Complete Metabolic Panel (corrected calcium for low albumin)
    - Corrected Calcium = 0.8 * (4 – Albumin) + Measured Calcium
  - Phosphorus
    - Rare disorders of low phosphorus, osteomalacia
  - Vitamin D (25 – OH)
  - PTH (parathyroid level)
  - TSH
- General recommendation
  - Magnesium
  - CBC
  - Spine x-ray (more than 1.5 inches of height loss over lifetime)
  - 24 hour urine calcium (kidney stones = hypercalciuria?)
- Not Recommended
  - Bone turnover markers (NTX, CTX)
  - Vitamin D (1,25 – OH)

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Osteoporosis Treatment - Calcium

- A vital component of care!
- Total daily MINIMUM = 800 mg from all sources combined
  - Dairy plus supplements
  - Maximum intake = 2000 mg
- Assume 250 mg of calcium for every serving of dairy
  - Soy, almond, and coconut milk must say FORTIFIED on the package
- Leafy green vegetables are a potential source of calcium
  - Collard Greens: 250 mg / cup
  - Turnip greens: 200 mg /cup
  - Kale / Bok Choy: 150 mg / cup
  - Spinach contains oxalate which will impede absorption of calcium
  - All other greens contain < 150 mg / cup (broccoli, okra, swiss chard, peas)

Osteoporosis Treatment - Calcium

- Supplement to a level of 800 mg daily if required with tablets/caplets/chews/liquid/powder
- Will not cause a heart attack
- Calcium carbonate – most common form
  - 1 serving = 1 tablet will provide 500-600 mg calcium
  - Take with food
- Calcium Citrate – enhanced absorption over calcium carbonate
  - 1 serving = 2 tablets will provide 500 mg calcium
- Jarrows Bone Up™, Osteoblend™ are acceptable
  - Large serving size (3-6 tablets) to provide 500-800 mg calcium

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Calcium Clinical Pearl

- PPIs (proton pump inhibitors) reduces absorption of calcium carbonate
  - H2 blockers (famotidine) not a concern
- Switch to Calcium Citrate based regimen
  - Citracal™ is my personal favorite
- Other conditions to consider calcium citrate
  - Post gastric bypass
  - Crohns or Inflammatory bowel disease
  - Gluten intolerance
- Remember, calcium citrate will require 2 tablets to provide 500-600 mg of calcium

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Osteoporosis Treatment – Vitamin D

- Goal Vitamin D (25 – OH) level
  - Optimal: 30 – 80 ng/ml (no difference between 34 and 68 ng/ml)
  - 20 ng/ml is absolute minimum
- 4000 IU (international units) daily from all supplement sources is safe and effective
- Add on 50,000 IU prescription dose weekly for 8 weeks to boost very low baseline levels (< 15 ng/ml)
- Check level after 6-8 weeks of repletion
- 6000 – 8000 IU daily are needed for some patients
  - No toxicity until levels over 100 ng/ml

Vitamin D Clinical Pearl

- Vitamin D3 (cholecalciferol) is the standard vitamin D supplement
  - Human/animal form
- Vitamin D2 (ergocalciferol) is plant based form
  - Same mechanism of action as D3 but shorter half-life
    - Vegan preferred
  - Prescription 50,000 IU capsule is Vitamin D2 – short term use
- Some labs report out Vitamin D3 (25-OH) and Vitamin D2 (25-OH) values
  - This is absurd, the total value (D3 (25-OH) + D2 (25-OH)) is what matters

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Osteoporosis Treatment - Exercise

- Best weight bearing exercise program:
- Oregon State University Better Bones and Balance Program
  - $15.00 workout DVD
  - https://extension.oregonstate.edu/bbb/better-bones-balancer-store#dvd

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Osteoporosis Medications Prologue

- CALCIUM, VITAMIN D, WEIGHT BEARING EXERCISE ARE THE FOUNDATIONS OF BONE HEALTH
  - Ensure that all three elements are addressed in your patient prior to medical therapy

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Osteoporosis Treatment – Medications Bisphosphonates

- Bisphosphonates enter bone matrix and inhibits osteoclast cells (bone eating cells)
  - Known as ANTI-RESORPTIVES
- 1) Alendronate 70 mg tablet by mouth once weekly
  - Generic for Fosamax™
  - No role for Actonel™ (risedronate) nor Boniva™ (ibandronate)
- Empty stomach, water only, no lying down for 30 minutes
  - Complex rules and GI side effects main barrier to usage
- Reduces spine, hip, and other fractures (humerus, radius, rib etc..)
- A first line agent

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Osteoporosis Treatment – Medications Bisphosphonates

- 2) Reclast™ (zoledronic acid) 5 mg infusion
- Once yearly
- 100% adherence, no gastrointestinal side effects
  - inexpensive
- Excellent fracture prevention
- Post infusion reaction 1 – 5 days post therapy
  - Flu like symptoms
  - Acetaminophen, hydration, rest

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Bisphosphonate Clinical Pearl

- Mild GERD not contraindication to oral alendronate
  - Safe to try for 4-8 weeks to assess GI side effects
- Caution patients on post infusion reaction to zoledronic acid infusion
- Ensure normal calcium levels and calcium intake
- Ensure normal vitamin D (25 – OH) level and vitamin D intake
- Minimum GFR for bisphosphonates: 40 ml/min
  - Calculate via Cockcroft-Gault equation
    - Accounts for weight, gender, age, and creatinine (MDRD does not account for weight)
    - Women less than 100 lbs will have low GFR despite normal creatinine

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Osteoporosis Treatment – Medications
Prolia™ (denosumab)

- Inhibits osteoclast signaling (only agent with this mechanism of action)
  - Classified as an anti-resorptive, like bisphosphonates
- 60 mg subcutaneous injection every 6 months
  - Must be in health care setting, not for patient self injection
- Superb spine, hip, and other fracture prevention
  - Similar to Reclast™ (zoledronic acid)
- Alternative for those with adverse reaction to bisphosphonates
  - Myalgias, infusion reaction
- Minimum GFR is 30 ml/min (excellent choice for CKD)

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Denosumab Clinical Pearls

- Need labs within 60 days prior to every injection to ensure normal calcium levels
- Can be ‘late’ 4-6 weeks for a scheduled injection
- No post injection reaction
- Ensure adequate calcium and vitamin D intake

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Osteonecrosis of the Jaw - ONJ (bisphosphonates and denosumab)

- Very rare: 4 in 10,000 patient-years
  - Fear of this adverse event not sufficient to avoid osteoporosis therapy
- Precautions
  - Poor dentition (you will know it when you see it)
  - History of radiation therapy to jaw/mouth
  - No regular dental care (unless full dentures)
  - Planned dental extraction or root canal
- Dental clearance not required
- No lab tests nor imaging available to predict, monitor for ONJ

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Surveillance / Monitoring of Therapy

- Bone density after 1 year of therapy
  - Same or improved values
    - No declines over 5 %
- Routine labs not required on oral bisphosphonates
  - Need labs for prior to each IV Reclast and SQ prolia administration

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Duration of Therapy

- Alendronate: Not to exceed 5 years of continuous therapy
- Zoledronic acid: Not to exceed 3 years of continuous therapy
- Prolonged bisphosphonate exposure increases risk of atypical mid-femur shaft fractures
  - 1/1000 risk after 8 years of therapy
- Can restart therapy after 2 year drug holiday
- Denosumab: Safety data up to 10 years (20 injections) continuously
  - Therapy cessation after 3 years associated with accelerated bone loss

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2nd Line Therapeutic Options

- Estrogen replacement (HRT)
- Prevents fractures
  - Breast and clot related side effects
- Should be used in conjunction with relief of menopausal symptoms
  - Should not be used solely for bone health
- Can be used in combination with any osteoporosis agent
  - Except raloxifene
- Rapid declines in bone mass occur after cessation

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2nd Line Therapeutic Options

- Evista™ (raloxifene) : Selective estrogen receptor modulator (SERM)
- 60 mg tablet daily
  - No regard to food or medications
- Prevents spine fractures
  - No hip fracture prevention data
- Reduces risk of breast cancer
  - If used for this indication, can be combined with other osteoporosis agents
- Risk of blood clots similar to estrogen
  - No uterine bleeding (progesterone not needed)

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Summary

- Calcium, Vitamin D, and weight bearing exercise are the foundations of bone health
  - Must be present for medical therapy to succeed
- Use calcium supplements to *supplement* to 800 mg of calcium daily
- Calculate FRAX score for patients with osteopenia
- Alendronate PO, zoledronic acid IV (Reclast), and denosumab SQ (Prolia) are the primary osteoporosis agents
  - Reclast and Prolia are within the purview of primary care providers
- Bisphosphonates (alendronate/zoledronic) have duration limits
- ONJ is a rare adverse effect
- Raloxifene and HRT are 2nd line agents
  - Raloxifene does not prevent hip fractures
  - HRT should be used in conjunction with menopausal symptom relief

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