Prevention and Treatment of Osteoporosis

Geetha Gopalakrishnan MD
Objectives

• Discuss clinical implications of osteoporosis
• Review WHO, NOF and USPSTF Guidelines
• Discuss prevention and treatment options
Osteoporosis

• Most common skeletal disorder
• Characterized by a progressive decrease in bone density, causing bones to become brittle, weakened, and easily fractured
WHAT CAUSES OSTEOPOOROSIS?

- Result of a "mismatch" between bone formation and resorption with aging
- Bone becomes abnormally thin and porous (Osteopenia/Osteoporosis)
- Increasing fragility and risk of fracture
NORMAL

OSTEOPOROSIS
SYMPTOMS OF OSTEOPOROSIS

• Asymptomatic
• Fracture
  – Wrist Fracture
  – Vertebral Fracture
  – Hip Fracture
• High morbidity and mortality
Dual Energy X-ray Absorptiometry

Central DEXA: 1-5 mrem
Background: 5-8 mrem
CXR: 50-150 mrem
Mammogram: 450 mrem
BONE HEALTH

![Bone Mass/Fracture Risk Graph]

- **Bone Mass/Fracture Risk**
- **Age**

Fracture range
1994 WHO CLASSIFICATION

Osteoporosis
Fragility Fracture

Osteopenia

Normal Bone Mass

T-score

-2.5

-1.0
Risk for Fracture

Ten Year Probability of Symptomatic Fracture (%)

Age 80
Age 70
Age 60
Age 50

Fracture Risk in Postmenopausal Women

“Osteoporotic” Fracture

-1.00
1.80*
4.03 †

*(CI = 1.49-2.18)
†(CI = 3.59-4.53)

Hip Fractures

1.00
2.70 *
8.9 †

*(CI = 2.14-3.40)
†(CI = 6.84-11.57)

Relative Risk

T-score by peripheral devices

N = 212,000

Fracture Risk in Postmenopausal Women

Fracture rate

- Fracture per 1000 Person-Years
- BMD distribution
- Fracture rate
- No. of women with fractures

Peripheral BMD T-Scores


Slide: NOF website
Treatment Guidelines

-2.5  Treatment based on risk factors  -1.0

T-score
Clinical Risk Factors

- Age
- Gender
- BMI
- BMD i.e. femoral neck
- Prior fragility fracture
- Corticosteroid use
- Family history of hip fracture
- Current smoker
- Alcohol intake > 3 units/day
- Secondary causes i.e. RA
Absolute Fracture Risk Assessment (FRAX)

• Combines independent risk factors for fracture in an algorithm that is assessable, convenient, and validated

• Provides a rational basis for therapy that can be adapted world-wide according to economic and other considerations
Welcome

The FRAX® tool has been developed by WHO to evaluate fracture risk of patients. It is based on individual patient models that integrate the risks associated with clinical risk factors as well as bone mineral density (BMD) at the femoral neck.

The FRAX® models have been developed from studying population-based cohorts from Europe, North America, Asia and Australia. In their most sophisticated form, the FRAX® tool is computer-driven and is available on this site. Several simplified paper versions, based on the number of risk factors are also available, and can be downloaded for office use.

The FRAX® algorithms give the 10-year probability of fracture. The output is a 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture).

Dr. John A Kanis
Professor Emeritus, University of Sheffield

Links:
Japan Osteoporosis Foundation: [http://www.jopf.or.jp/](http://www.jopf.or.jp/)
FRAX - WHO Fracture Risk Assessment Tool - Microsoft Internet Explorer

Welcome

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Links:
- International Osteoporosis Foundation: http://www.iotbonehealth.org/
- National Osteoporosis Foundation: http://www.nof.org/
- Japanese Osteoporosis Foundation: http://www.jopf.or.jp/

© World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield, UK
The New FRAX Tool

Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

**Country:** US (Caucasian) **Name / ID:**

**Questionnaire:**

1. Age (between 40-90 years) or Date of birth
   - Age: [76]  
   - Date of birth: [Y: , M: , D: ]

2. Sex  
   - Male  
   - Female

3. Weight (kg)  
   - [61.23]

4. Height (cm)  
   - [165.1]

5. Previous fracture  
   - No  
   - Yes

6. Parent fractured hip  
   - No  
   - Yes

7. Current smoking  
   - No  
   - Yes

8. Glucocorticoids  
   - No  
   - Yes

9. Rheumatoid arthritis  
   - No  
   - Yes

10. Secondary osteoporosis  
    - No  
    - Yes

11. Alcohol 3 or more units per day  
    - No  
    - Yes

12. Femoral neck BMD (g/cm²)  
    - Hologic: 0.630  
    - T-score: -1.9

**T-score:**

- Major osteoporotic: 19
- Hip fracture: 3.8

With BMD

- Major osteoporotic
- Hip fracture

**Weight Conversion:**
- 135 pounds = 61.23 kg

**Height Conversion:**
- 65 inches = 165.1 cm
Initiate therapy if 10-yr risk
- Major fracture ≥ 20%
- Hip fracture ≥ 3%
Limitation of FRAX

• Not applicable in premenopausal women or men under 50 years

• Does not apply to patients already taking an pharmacological medication
**World Health Organization**

**National Osteoporosis Foundation**

<table>
<thead>
<tr>
<th>T-score</th>
<th>Postmenopausal women</th>
<th>Men &gt; 50 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>-2.5 or below Fragility fracture</td>
<td>Pharmacological therapy</td>
<td>Pharmacological therapy if 10-year risk</td>
</tr>
<tr>
<td>-1.0 to -2.5</td>
<td>Pharmacological therapy</td>
<td>Major fracture ≥ 20%</td>
</tr>
<tr>
<td>Above -1.0</td>
<td>Prevention of osteoporosis</td>
<td>Hip fracture ≥ 3%</td>
</tr>
</tbody>
</table>
Prevention and Treatment

Assess and modify risk factors and secondary causes for bone loss and fracture

Maintain Calcium and Vitamin D
Encourage exercise
## Treatment of Osteoporosis

<table>
<thead>
<tr>
<th>Medicine</th>
<th>BMD</th>
<th>Fracture</th>
<th>Side Effect</th>
</tr>
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<tbody>
<tr>
<td>Alendronate</td>
<td>↓ Spine</td>
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<td>Rhinitis</td>
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<td>Epistaxis</td>
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<td>↓ in new vertebral fx</td>
<td>Osteosarcoma</td>
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<td>↓ in new vertebral fx</td>
<td>Atypical infections</td>
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<td></td>
<td></td>
<td>↓ in hip fx</td>
<td>Hypocalcemia</td>
</tr>
</tbody>
</table>
Case Presentation #1

55 year old postmenopausal women with a family history of hip fracture is referred for evaluation of her bone health. What next?
### Risk Assessment

#### RISK FACTORS
- Personal history of fracture
- Fracture in first degree relative
- Current cigarette smoking
- Low body weight (127lbs)
- Oral steroid therapy > 3mo
- Early estrogen deficiency (< 45)
- Lifelong low calcium intake
- Alcoholism (>2 drinks/day)
- Inadequate physical activity
- Recurrent falls
- Dementia
- Impaired eye sight
- Poor health/ frailty

#### MEDICATIONS
- Glucocorticoids
- Progesterone
- GNRH agonists
- Anticonvulsants
- Immunosuppressants

#### MEDICAL CONDITIONS
- Hypogonadism/Anorexia
- Hyperparathyroidism/CRF
- Thyrotoxicosis/Diabetes
- Rheumatoid arthritis
- HIV/AIDS
- IBS/Malabsorption/Sprue
Bone Mineral Density

Fragility Fracture

Men greater than 70 years

Postmenopausal women greater than 65 years

Postmenopausal women less than 65 years and Men 50-69 years with risk factors

Premenopausal women and men with secondary cause

Case #1: 55 year old PMW with a family history of hip
# Osteoporosis Screening Recommendations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women</strong></td>
<td><strong>Men</strong></td>
</tr>
<tr>
<td>NOF</td>
<td>BMD testing for all women ≥65 yrs and postmenopausal women &lt;65 yrs based on risk factor profile</td>
</tr>
<tr>
<td>ACOG</td>
<td>BMD testing for all women ≥65 yrs and postmenopausal women &lt;65 yrs who have 1 or more risk factors</td>
</tr>
<tr>
<td>USPSTF</td>
<td>Screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors (FRAX &gt; 9.3%)</td>
</tr>
</tbody>
</table>
U.S. Preventive Services Task Force

Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

Country: US (Caucasian)  Name/ID:  

**Questionnaire:**

1. Age (between 40-90 years) or Date of birth
   - Age: 55
   - Date: Y:  M:  D:  

2. Sex  
   - Male  Female

3. Weight (kg): 61.23

4. Height (cm): 165.1

5. Previous fracture  
   - No  Yes

6. Parent fractured hip  
   - No  Yes

7. Current smoking  
   - No  Yes

8. Glucocorticoids  
   - No  Yes

9. Rheumatoid arthritis  
   - No  Yes

10. Secondary osteoporosis  
    - No  Yes

11. Alcohol 3 or more units per day  
    - No  Yes

12. Femoral neck BMD (g/cm²)  
    - Select DXA

BMI 22.5
The ten year probability of fracture (%)

- Major osteoporotic: 11
- Hip fracture: 0.6

Screening DXA if FRAX > 9.3%
Case #1: T-score of -2.3 FN and -1.9 spine
Prevention of Osteoporosis

Assess and modify risk factors and secondary causes for bone loss and fracture

Maintain Calcium and Vitamin D
Encourage exercise
Calcium Intake

• Recommendations
  – 1000-1200 mg

• Dietary sources of calcium
  – Estimating dietary calcium intake
    • Multiplying the number of dairy servings by 300 mg
    • Serving: 8 oz milk/yogurt, 1 oz hard cheese, 16 oz cottage cheese, 1 cup spinach and broccoli

• Supplements
  – Multivitamin
  – Elemental Calcium
    • Calcium carbonate
    • Calcium citrate
### Supplemental Source of Calcium

<table>
<thead>
<tr>
<th>Calcium Salts</th>
<th>Elemental calcium per gram</th>
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</thead>
<tbody>
<tr>
<td>Calcium acetate</td>
<td>250 mg</td>
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<tr>
<td>Calcium carbonate</td>
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<tr>
<td>Calcium chloride</td>
<td>270 mg</td>
</tr>
<tr>
<td>Calcium citrate</td>
<td>211 mg</td>
</tr>
<tr>
<td>Calcium glubionate</td>
<td>64 mg</td>
</tr>
<tr>
<td>Calcium gluconate</td>
<td>90 mg</td>
</tr>
<tr>
<td>Calcium lactate</td>
<td>130 mg</td>
</tr>
<tr>
<td>Calcium phosphate</td>
<td>390 mg</td>
</tr>
</tbody>
</table>

*Example: 1000mg of calcium carbonate has 400 mg of elemental calcium*
Intestine

Bo

Kidn

e

y

K

id

ey

Ca

l

l

c

ciferol

chola

7-dehydrocholesterol

Diet

UV

Diet

Calcium/Vitamin D Homeostasis

PTH

Bone

Liver

25 D

1,25 D

Vitamin D

Ca + PO4

Ca + PO4

CaPO4

CaPO4

Ca + PO4

CaPO4

CaPO4

Calcium

cholecalciferol

7-dehydrocholesterol
Vitamin D Deficiency

Prevalence
- Overt rare
  - Hypocalcemia
  - Hypophosphatemia
  - Rickets or osteomalacia
- Subclinical common
  - Osteoporosis

Contributing Factors
- Cutaneous production
  - Declines with age
  - Varies with season, latitude, and skin pigmentation (UV light)
- Reduced Vitamin D intake
  - 50% consume <137 IU/d
  - 25% consume <65IU/d

Holick MF, JCEM2005
Vitamin D Deficiency

Biochemical criteria

- Reference normal values of 10 to 50 ng/mL
- Serum 25-hydroxyvitamin D concentration of <30 ng/mL suggestive of deficiency
Fracture Prevention

Calcium 1200mg and Vitamin D 800IU/day
-43% reduction in hip fracture
-34% reduction in non vertebral fracture

**Figure 2** Cumulative probability of hip fracture and other nonvertebral fracture in elderly women treated with placebo (open squares) or vitamin D₃ plus calcium. (From Chapuy et al., *N. Engl. J. Med.* 327, 1640 (1992).)
Recommendation

- Check Vitamin D25 level
  - Postmenopausal women
  - Men/premenopausal women if Z score \(< -2.0\) or risk factors
- Less than 20-30ng/ml
  - Treat with Vitamin D 50,000IU per week for 8 weeks
  - Repeat level and retreat if necessary
- Greater than 30ng/ml
  - Recommend Vitamin D 800IU/day
  - Supplements: MVI or calcium+D
  - Dietary vitamin D
    - Vitamin D-fortified dairy products, egg yolks, saltwater fish and liver
    - Milk 100 IU/serving
  - Sun exposure
    - 10-15 minutes exposure of hands, arms and face two to three times a week
Exercise

• Young women (mean 21yrs)
  – Gymnastics for 8mo
  – Gained 2% lumbar spine and 1.6% femoral neck

• Premenopausal women (35-45yrs)
  – High impact aerobics 3 times week for 18 mo
  – Increase in BMD at femoral neck versus controls

• Postmenopausal women (50-70yrs)
  – Strength training for one year
  – Gain in lumbar spine 1.0% and femoral neck 0.9%

• 8600 women (mean 73yrs)
  – Active exercise for 1 hr per day vs. <0.5hrs per day
  – Decrease risk of hip fracture (RR 0.6)
Exercise

• Exercises are important for building and maintaining bone mass
  – Weight-bearing
    • Bones/muscles work against gravity
    – Jogging, walking, stair climbing, dancing and soccer
    – Swimming and bicycling are not weight-bearing
  – Resistance
    • Muscular strength to strengthen bone
    – Free weights
    – Weight machines found at gyms

• Engage in appropriate exercise for at least 30 minutes three times per week
Prevention of Osteoporosis

Maintain Calcium and Vitamin D
Encourage exercise

Assess and modify risk factors and secondary causes for bone loss and fracture
Case Presentation # 2

81 year old female with no prior history of fractures is referred for evaluation of osteopenia. A T-score of -1.4 at hip and -1.2 at the spine is noted. What next?
Prevention of Osteoporosis

Maintain Calcium and Vitamin D
Encourage exercise

Assess and modify risk factors and secondary causes for bone loss and fracture
Preventing falls

- One third of individuals 65 years of age or older will fall each year
- 90% of hip fractures result from falls
- Measures to help prevent falls plays an important role in decreasing the frequency of fractures.
  - Remove rugs and cords that could lead to fall
  - Ensure adequate lighting and encourage eye exam
  - Review and alter drug regimens to minimize falls
Case 2

81 year old female with no prior history of fractures and a T-score of -1.1 at femoral neck and -1.2 at spine.
### Treatment and Fractures

<table>
<thead>
<tr>
<th>Agent</th>
<th>Vertebral</th>
<th>Nonvert</th>
<th>Hip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogen</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Alendronate</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
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<td>+</td>
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<td>+</td>
</tr>
<tr>
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<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
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<td>+</td>
<td>-</td>
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</table>
Bisphosphonates

Etidronate

Clodronate

Tiludronate

Pamidronate

Alendronate

Olpadronate

Ibandronate

EB-1053

Risedronate
Bisphosphonates

• Increases bone mass
• Reduces vertebral and nonvertebral fractures*
• Oral Preparations
  – Alendronate (Fosamax)*
  – Risedronate (Actonel)*
  – Ibandronate (Boniva)
• Intravenous Preparations
  – Ibandronate (Boniva)
  – Zolendronate (Reclast)
• Other options: Pamidronate, Etidronate and Tiludronate
• SE: GI discomfort, Osteonecrosis of the jaw
OSTEONECROSIS OF THE JAW

Clinical presentation:

• Infection and necrotic bone in the mandible
• One-third of the lesions are painless
• Often seen following steroid use, radiation, cancer, dental extraction, local infection, or trauma, although it can occur spontaneously
• Associated with bisphosphonate therapy
ONJ and Comparative Risks

Risk per 100,000 People per Year

- Any Fragility Fracture: 2668
- Hip Fracture: 387
- Anaphylaxis from PCN Shot: 32
- Death by MVA: 11
- Death by Murder: 6
- ONJ - Osteoporosis Patient: 0.7
- Death by Lighting Strike in NM: 0.6

Recommendations

- Identify and rectify dental problems prior to treatment
- Oral hygiene status should be monitored during treatment
- Diagnosis of ONJ:
  - Management: Surgical resection of necrotic bone and antibiotic therapy
  - Discontinuing bisphosphonate therapy is debated
Frozen Bone: Theoretical

- Prolonged bisphosphonate therapy may lead to over suppression of bone turnover and increased skeletal fragility
  - High-dose bisphosphonate accumulation results in microscopic damage in animal studies
  - Case reports of atypical fracture (particularly sub-trochanteric fractures) and severely suppressed bone turnover have been reported in the setting of prolonged bisphosphonate therapy
- Observed association do not prove causality
Atypical Femoral Fractures
Duration of Therapy

• Fracture Intervention Trial Long-term Extension (FLEX)
• 1099 PMW who had previously received alendronate for five years in the Fracture Intervention Trial (FIT)
  – Randomized to additional 5yrs of alendronate or placebo
  – Women who were switched to placebo after five years
    • Gradual decline in BMD
    • Increase in markers of bone turnover
    • Rate of non-vertebral or vertebral fractures was not different
  – Does not address the impact of stopping therapy in women at highest risk for fracture (excluded from the trial).
## Treatment of Osteoporosis

<table>
<thead>
<tr>
<th>Drug</th>
<th>BMD</th>
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<th>Side Effect</th>
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Guideline

Postmenopausal Women
- Maintain Calcium and Vitamin D
- Encourage exercise
- Assess risk factors and secondary causes for bone loss

Men ≥ 50 years
- Maintain Calcium and Vitamin D
- Encourage exercise
- Assess risk factors and secondary causes for bone loss
Who Should Undergo Testing?

Bone Mineral Density

- Fragility Fracture
- Men greater than 70 years or 50-69 years with risk factors
- Postmenopausal women greater than 65 years
- Postmenopausal women less than 65 years with risk factors (FRAX > 9.3%)
- Premenopausal women and men with secondary cause
Who Should Be Treated?

DXA

Normal
T score > -1.0

Lifestyle Modification

Osteopenia
T score -1 to -2.5

Pharmacological therapy in high risk individuals

Osteoporosis
T score < -2.5
Fragility Fracture

Pharmacological Therapy
<table>
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<tr>
<th>T-score</th>
<th>Postmenopausal women</th>
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<td>- Major fracture ≥ 20%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Hip fracture &gt; 3%</td>
</tr>
<tr>
<td>-1.0 to -2.5</td>
<td></td>
<td>Prevention of osteoporosis</td>
</tr>
<tr>
<td>Above -1.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MONITORING TREATMENT

• Monitor changes in BMD by DXA
  – After 1- 2 years
  – Changes due to precision error
    • 2 - 4% in the vertebrae
    • 3 - 6% at the hip
  – Repeat measurements on same equipment
Questions?