OSTEOPOROSIS

in
MEN

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Disclosure

Louis Kuritzky has NO RELATIONSHIPS TO DISCLOSE relevant to this presentation

Objectives

• Recognize limitations of relying upon BMD alone to Dx and Rx osteoporosis
• Appropriately identify men who merit BMD screening
• Choose treatments for men with osteoporosis
Reassess Periodically

OSPS At-Risk♂

Exercise

CA++ & vit D

T score > -1.0
Z score > -2.0

DEXA

Osteopenia (FRAX Score +) OR Osteoporosis (T-Score ≤ -2.5)

Bisphosphonate

Denosumab Teriparatide

Other

With Thanks To:

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With Thanks To:

Clinician’s Guide to Prevention and Treatment of Osteoporosis
Cosman F, de Beur SJ, LeBoff MS, Lewiecki EM, Tanner B, Randall S, Lindsay R
Osteoporosis International 2014 (August 15)
DOI:10.1007/x00198-014-2794-2

Definitions & Scope of the Problem
OSPS: Definition

“OSPS is a condition in which the bones have a propensity to fracture spontaneously or as a result of minimal trauma. In this condition…there is too little bone tissue to provide adequate skeletal support for the physical stresses of normal daily life…”

Barzel US “Osteoporosis” Conn’s Current Therapy Saunders (Philadelphia) 2007:714-718

Finding Osteoporosis: Is That Enough?

“…the majority of fractures occur in patients with low bone mass rather than osteoporosis, because of the large number of individual with bone mass in this range.”

Osteoporosis: Scope of the Problem (USA)

- Osteoporosis: 9.9 million
- Osteopenia: 43.1 million
- Caucasian women lifetime Fx risk: 1/2
- Caucasian men lifetime Fx risk: 1/5
- African Americans: less frequent low BMD than Caucasians, but similar risk at same BMD


Hip Fx: Mortality

“Hip fractures are associated with an 8-36% excess mortality within 1 year, with a higher mortality in men than in women.”

### Osteoporosis Dx: WHO Guidelines

**Comparing BMD to Mean BMD of Healthy Young White Women**

<table>
<thead>
<tr>
<th>Level</th>
<th>SD Below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 1 SD below</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>≥ 1 - 2.5 SD below</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>≥ 2.5 SD below</td>
</tr>
<tr>
<td>Severe osteoporosis</td>
<td>≥ 2.5 SD below + fractures</td>
</tr>
</tbody>
</table>


### World Health Organization (WHO) Osteoporosis Guidelines

**T-Score**

NORA: Fracture Rates, BMD Distribution and Number of Fractures

BMD T-scores

Siris ES et al., JAMA 2001;286:2815-22

N=200,160

Fracture Rate

BMD distribution

N=200,160

Siris ES et al., JAMA 2001;286:2815-22.
NORA: Fracture Rates, BMD Distribution and Number of Fractures

Fracture Rate

# Fractures

BMD T-scores

N=200,160

Siris ES et al., JAMA 2001; 286:2815-22.

NORA: Fracture Rate Ratios

<table>
<thead>
<tr>
<th>Fx type</th>
<th>OSPS:WNL</th>
<th>OSPS:OSPN</th>
<th>OSPN:WNL</th>
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<tbody>
<tr>
<td>Any</td>
<td>4.03</td>
<td>2.24</td>
<td>1.80</td>
</tr>
<tr>
<td>Hip</td>
<td>8.90</td>
<td>3.30</td>
<td>2.70</td>
</tr>
<tr>
<td>Spine</td>
<td>5.00</td>
<td>2.65</td>
<td>1.89</td>
</tr>
<tr>
<td>Wrist</td>
<td>5.32</td>
<td>1.92</td>
<td>2.77</td>
</tr>
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</table>

### Age Trumps T-Score

**10 Year Fracture Probability in Swedish Women**

<table>
<thead>
<tr>
<th>Age</th>
<th>T Score 0</th>
<th>T Score -0.5</th>
<th>T Score -1.0</th>
<th>T Score -1.5</th>
<th>T Score -2.0</th>
<th>T Score -2.5</th>
<th>T Score -3.0</th>
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<tr>
<td>50</td>
<td>3.8</td>
<td>4.7</td>
<td>5.9</td>
<td>7.4</td>
<td>9.2</td>
<td>11.3</td>
<td>14.1</td>
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<tr>
<td>55</td>
<td>4.1</td>
<td>5.3</td>
<td>6.7</td>
<td>8.5</td>
<td>10.7</td>
<td>13.4</td>
<td>16.8</td>
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<tr>
<td>60</td>
<td>5.1</td>
<td>6.5</td>
<td>8.2</td>
<td>10.4</td>
<td>13.0</td>
<td>16.2</td>
<td>20.2</td>
</tr>
<tr>
<td>65</td>
<td>6.3</td>
<td>8.0</td>
<td>10.0</td>
<td>12.6</td>
<td>15.6</td>
<td>19.3</td>
<td>23.9</td>
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<tr>
<td>70</td>
<td>7.1</td>
<td>9.0</td>
<td>11.5</td>
<td>14.6</td>
<td>18.3</td>
<td>22.8</td>
<td>28.4</td>
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<tr>
<td>75</td>
<td>7.0</td>
<td>9.1</td>
<td>11.8</td>
<td>15.2</td>
<td>19.4</td>
<td>24.5</td>
<td>30.8</td>
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<tr>
<td>80</td>
<td>7.7</td>
<td>9.9</td>
<td>12.7</td>
<td>16.2</td>
<td>20.5</td>
<td>25.6</td>
<td>31.8</td>
</tr>
</tbody>
</table>


### NORA: Summary/Conclusions

- Women with the lowest BMD have the highest *RATE* of fracture
- HOWEVER: 50% of osteoporosis fractures occur in women with T-scores above –2.5
- Identifying the high risk osteopenic patient has become a priority

*Siris ES et al. JAMA 2001; 286:2815-22.*

**World Health Organization (WHO) Osteoporosis Guidelines**

**Men vs Women**

**Post-Peak Bone Loss Patterns**

**Women**
- 0.3%-0.5% yearly until menopause
- 1%-2% at menopause up to 5%

**Men**
- 0.2%-0.5% yearly

Bone Mass Through the Life Span


Hip Fx: Outcomes

Barzel US “Osteoporosis” Conn’s Current Therapy
Saunders (Philadelphia) 2007:714-718
National Osteoporosis Foundation Recommendations 2014

NOF 2014: Universal Recommendations (Applies to Men ≥50 yrs)

- Counsel on risk of OSPS and related Fx
- Check for secondary causes of OSPS
- Advise on Diet
  - Age 50-70: Ca++ ≥1000 mg/d
  - Age ≥71: Ca++ ≥1200 mg/d
  - Vitamin D: 800-1000 u/d
  - Add supplement if diet insufficient

Ca++: When Mae West Was Wrong

“Intakes [of Ca++] in excess of 1200-1500 mg/d may increase the risk of developing kidney stones, CV disease, and stroke.”

NOF 2014: Universal Recommendations
(Appplies to Men ≥50 yrs)

- Recommend weight-bearing and muscle-strengthening exercise for
  ♦ Improved agility, strength
  ♦ Improved posture and balance
  ♦ Improved bone strength
  ♦ Reduced risk of falls & Fx
Indications for BMD

- Men > 70, regardless of risk factors
- Men 50-69 with risk factors
- Adults ≥50 incurring Fx
- $2^0$ causes of OSPS (eg, RA, hypogonadism)
- Meds (e.g., prednisone)

NOF 2014: Diagnostic Assessment

- Measure height annually
- Check for $2^0$ causes of osteoporosis
- BMD (performed at qualified DXA facility)
  - All men ≥ 70 yrs
  - Men age 50-69 with risk factors
  - Men who have had an adult Fx
  - Meds (e.g., prednisone ≥5mg/d x ≥90 d)
**FRAX OSPS Clinical Risk Factors**

- Age
- Gender
- Fx Hx
- BMD (Femur)
- BMI

- Oral Glucocorticoids
- FHx Hip Fx
- Smoking
- Alcohol ≥ 3 drinks/d
- $2^0$ OSPS (e.g., RA)

The WHO Fracture Risk Assessment Tool (www.shef.ac.uk/FRAX)

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**Indications to Consider Vertebral Imaging**

- Men ≥80 with T-score ≤ -1.0 at any site
- Men age 70-79 if T-score ≤ -1.5 at any site
- Men ≥50 with
  - Low-trauma Fx
  - Historical height loss ≥ 1.5 in
  - Prospective height loss ≥ 0.8 in
  - Long-term glucocorticoid Rx

Vertebral Imaging

- After baseline, repeat if
- Prospective height loss documented
- New back pain
- Drug holiday planned (no holiday if recent Fx)

Potential Lab for 20 OSPS Causes

<table>
<thead>
<tr>
<th>Result</th>
<th>Test</th>
<th>Condiunset</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC</td>
<td>Thyroid Function Tests</td>
<td>Serum immunofixation</td>
</tr>
<tr>
<td>CA++</td>
<td>Vit D (25(OH))</td>
<td>Serum-free light chains</td>
</tr>
<tr>
<td>BUN/Cr</td>
<td>Urine free cortisol</td>
<td>Celiac screen</td>
</tr>
<tr>
<td>PO4--</td>
<td>Testosterone</td>
<td>Fe++ &amp; Ferritin</td>
</tr>
<tr>
<td>Mg++</td>
<td>Bone turnover markers</td>
<td>Prolactin</td>
</tr>
<tr>
<td>LFTs</td>
<td>SPEP</td>
<td>Tryptase</td>
</tr>
<tr>
<td>PTH</td>
<td>Urine histamine</td>
<td>UPEP</td>
</tr>
</tbody>
</table>

Who To Treat

Unmet Needs in OSPS: Why?

“BMD has traditionally been used for the Dx of OSPS and as a measure of fracture risk. However, relying ONLY on BMD to identify those at risk neglects a considerable proportion of [persons] in need of therapy.”

Levine K “Effective strategies to identify postmenopausal women at risk of osteoporosis” Geriatrics 2007;62(11):22-30
“Osteoporosis…is a risk factor for fracture just as hypertension is for stroke.”

“The majority of fractures, however, occur in patients with low bone mass rather than osteoporosis.”

Clinician’s Guide to Prevention and Treatment of Osteoporosis
www.nof.org accessed 08-July-20

NOF 2014: Whom to Treat

After exclusion of secondary causes, treat men age 50 and older who have...

Osteoporosis
Clinical diagnosis: Hip or spine fracture

DXA diagnosis:
T-score -2.5 or below in the spine or hip

T-scores between -1.0 and -2.5 and

10-year FRAX risk of fractures:
≥3% for hip fracture
or
≥20% for a major osteoporotic fracture
Indications for Pharmacologic Rx

- Hip or vertebral Fx (clinical or incidental)
  - evidence in osteoporosis or osteopenia
- T-score < -2.5
- T-score -1.0 to -2.5 at femoral neck or Lspine & 10-yr FRAX positive (3% hip, 20% any)

FRAX OSPS Clinical Risk Factors

- Age
- Gender
- Fx Hx
- BMD (Femur)
- BMI
- Oral Glucocorticoids
- FHx Hip Fx
- Smoking
- Alcohol ≥ 3 units/d
- $2^0$ OSPS (e.g., RA)

The WHO Fracture Risk Assessment Tool (www.shef.ac.uk/FRAX)
FRAX® Risk Factor Questions

• Prior fracture
Denotes a previous adult fracture after age 40 occurring with little or no trauma – fractures of face, fingers, toes excluded

• Systemic corticosteroids
Current, intended, or long-term past use of systemic steroids (> 5mg/d prednisone equivalent for > 3 months)

\(^1\)NOF FRAX Implementation Guide www.nof.org
FRAX Caveats: Entering Bone Density Data

Select DXA manufacturer and enter FEMORAL NECK BMD (g/cm²)

FRAX Results: Left Hip Summary

<table>
<thead>
<tr>
<th>Region</th>
<th>Area cm²</th>
<th>BMC g</th>
<th>BMD g/cm²</th>
<th>T-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck</td>
<td>5.67</td>
<td>0.66</td>
<td>-0.20</td>
<td></td>
</tr>
<tr>
<td>Trochanter</td>
<td>12.72</td>
<td>3.74</td>
<td>0.66</td>
<td>-0.18</td>
</tr>
<tr>
<td>Total</td>
<td>44.74</td>
<td>30.23</td>
<td>0.657</td>
<td>-1.2</td>
</tr>
</tbody>
</table>

Two-year probability of osteoporotic fractures (%) according to BMD T-score at the femoral neck in women from the UK.

Age = 50 years

<table>
<thead>
<tr>
<th>Number of Cases</th>
<th>BMD T-score (femoral neck)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-4.0</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
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<tr>
<td>2</td>
<td>20</td>
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<tr>
<td>2</td>
<td>17</td>
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<td>2</td>
<td>19</td>
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<tr>
<td>2</td>
<td>20</td>
</tr>
</tbody>
</table>

Age = 55 years

<table>
<thead>
<tr>
<th>Number of Cases</th>
<th>BMD T-score (femoral neck)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-4.0</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
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<td>2</td>
<td>20</td>
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<td>2</td>
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<tr>
<td>2</td>
<td>20</td>
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</tbody>
</table>

© World Health Organization Collaborating Centre for Metabolic Bone Diseases, University of Sheffield, UK.
FRAX: Secondary Osteoporosis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperthyroidism</td>
<td>Hypogonadism</td>
</tr>
<tr>
<td>Premature menopause</td>
<td>Chronic malnutrition</td>
</tr>
<tr>
<td>Malabsorption</td>
<td>Chronic liver disease</td>
</tr>
<tr>
<td>Osteogenesis Imperfecta</td>
<td>T1DM</td>
</tr>
</tbody>
</table>

FRAX Alcohol RF: >3 units/d

1 alcohol unit
- 8-10 g alcohol
- 285 ml beer
- 30 ml spirits
- 120 ml wine
- 60 ml apertif
Treatment

NOF 2014: Universal Recommendations
(Applies to Men ≥50 yrs)

- Assess RF for falls and offer modifications, eg
  - Home safety assessment
  - Balance training exercises
  - Correction of vitamin D insufficiency
  - Avoiding CNS depressants
  - Monitor antihypertensives
  - Correct vision

**NOF 2014: Universal Recommendations**
(Appplies to Men ≥50 yrs)

- Tobacco cessation
- Alcohol moderation

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**Rx of Suboptimal Vitamin D**

- **Goal:** Vitamin D level [25(OH)D] ≥ 30 ng/ml
- Vitamin D2 or vitamin D3 X 8-12 weeks
  - 50,000 IU/wk
  - 7,000 IU/d
- When 25(OH)D 30 ng/ml: 1500-2000 IU/d
- Maintenance dose may vary

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"There is no consistent evidence, to our knowledge, that calcium supplementation affects BMD in men, despite male osteoporosis being a common clinical problem."

Ca++ Supplementation: Healthy Men

- Study: RDBPCT healthy men (n=323)
- Exclusion: Zscore <-2.0
- Rx: Ca++ 600 mg 1200 mg/d vs placebo
- Outcome: BMD

Reid IR et al Arch Intern Med 2008;168(20):2276-2282

Ca++ Supplementation in Healthy Men

Reid IR et al Arch Intern Med 2008;168(20):2276-2282
Ca++ Supplementation: Healthy Men

Reid IR et al Arch Intern Med 2008;168(20):2276-2282

Pharmacologic Rx: FDA Approved in Men

- Alendronate (Fosomax)
- Risedronate (Actonel, Atelvia)
- Zoledronic acid (Reclast)
- Teriparatide (Forteo) up to 24 months
- Denosumab (Prolia)

**Choice of Pharmacologic Rx: Men**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Rx</th>
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<tbody>
<tr>
<td>General</td>
<td>alendronate, risedronate, zoledronic acid, teriparatide</td>
</tr>
<tr>
<td>Prostate CA ADT</td>
<td>denosumab</td>
</tr>
<tr>
<td>Recent hip Fx</td>
<td>zoledronic acid</td>
</tr>
<tr>
<td>FDA-approved Rx failure or contraindication</td>
<td>non-FDA approved methods (e.g, calcitonin, ibandronate, strontium ranelate)</td>
</tr>
</tbody>
</table>


**OSPS Rx in Men**

- **STUDY**: Osteoporotic men (n=241)
- **Rx**: alendronate 10 mg, Ca++, Vit D X 2 years

**BMD OUTCOME**: alendronate Placebo

- LS spine  \( \uparrow 7.1\% \)  \( \uparrow 1.8\% \)
- Femoral neck  \( \uparrow 2.5\% \)  \( \downarrow \)
- Hip Trochanter  \( \uparrow 4.4\% \)  \( \uparrow 1.3\% \)

**VERTEBRAL Fx OUTCOME**: 0.8% vs 7.1%

Nonvertebral Fx within 12 months Rx

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>91</th>
<th>183</th>
<th>274</th>
<th>365</th>
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<tbody>
<tr>
<td>4.0</td>
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<td>3.5</td>
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<tr>
<td>0.5</td>
<td></td>
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</tbody>
</table>

Fx Incidence %

Days

N=43,135

>90% White ♀ 4% ♂


Pharmacologic Rx: Drug Safety

- Bisphosphonates
  - Contraindicated with eGFR <30-35
  - zoledronic acid also contraindicated with ‘acute renal impairment’
  - Osteonecrosis: risk ↑ when Rx >5years
  - Thigh/groin pain: atypical femur Fx
- Denosumab: hypocalcemia (check preRx)

Pharmacologic Rx: How Long?

“No pharmacologic therapy should be considered indefinite in duration.”

NOF 2014: Pharmacologic Rx Duration

“No pharmacologic therapy should be considered indefinite in duration. After the initial Rx period, which depends on the pharmacologic agent, a comprehensive risk assessment should be performed….decisions need to be individualized.”
Considerations for Rx Beyond 5 Yrs

- Limited data
- Duration must be individualized
- Osteonecrosis and atypical femur Fx↑
- Consider continued Rx for ‘high risk’
  - Progressive height loss
  - BMD decline

Long-Term Monitoring

- Height: annual
- DXA: q2yrs
- Vertebral imaging
  - new back pain
  - documented prospective height loss
  - incidental Fx seen on CXR
  - during drug holiday
NOF 2014: Monitoring

- BMD q1-2 yrs after Rx initiation
- BMD q 2 years long term
- Interval may be longer if no major RF and Tscore WNL or ‘upper low bone mass range.’
- May repeat bone markers to confirm Rx effect


Bisphosphonate Holidays

- In patients at high risk for fractures, continued treatment seems reasonable. Consider a drug holiday of 1 to 2 years after 10 years of treatment

- For lower risk patients, consider a “drug holiday” after 4 to 5 years of stability

- Follow BMD and bone turnover markers during a drug holiday period, and reinitiate therapy if bone density declines or markers increase

1AACE Postmenopausal Guideline Endocr Practice 2010;16 (Suppl 3)
What is THIS?

Johnson K Fam Pract News 2005(May1):58

What is THIS?

Johnson K Fam Pract News 2005(May1):58
Bisphosphonates & Osteonecrosis

Osteonecrosis

- Seen most in myeloma or bone-metastatic CA
- Usually in patients receiving IV bisphosphonate (for hypercalcemia of malignancy) having dental work
- Rare overall; very rare with oral bisphosphonates (estimated 0.7 cases /100,000 person-years)

Levine K “Effective strategies to identify postmenopausal women at risk of osteoporosis” Geriatrics 2007;62(11):22-30
10-Year Probabilities of Osteonecrosis of the Jaw (ONJ) and Other Adverse Outcomes

- Major Osteoporotic Fx: 29%
- Fatal MVA: 0.15%
- Murder: 0.06%
- ONJ: 0.007%

The chart above illustrates the probabilities of various outcomes over a 10-year period. ONJ is listed with the lowest probability, followed by Murder and then Fatal MVA.


Hips Fx Prevention: Hip Protectors

- **STUDY**: frail senior adults (n= 1409 women, 392 men, mean age 82)
- **Rx**: Hip protector padded undergarment
- **MEASURED**: Rx group Hip Fx when Fx number in control group = 62 (= 2 years)
- **RESULTS**: Relative hazard in hip protector group= 0.4 (includes non-compliant Fx)

"Biochemical markers of bone turnover can aid in risk assessment and serve as an additional monitoring tool when treatment is initiated."

**Bone Turnover Markers**

- **Resorption markers**
  - C-telopeptide (serum)
  - N-telopeptide (urine)
- **Formation markers**
  - Bone-specific alkaline phosphatase
  - Osteocalcin
  - Type I procollagen propeptide
Bone Turnover Makers: Use

- Fasting AM specimen preferred
- Prediction capacity
  - Fx > BMD alone (unRx pt)
  - Rapidity of bone loss (unRx pt)
  - Fx risk reduction at 3-6 months Rx
  - Magnitude of BMD gain
- May help monitor compliance
- May help determine drug holiday duration


Exercise

OSPS At-Risk♂

CA++ & vit D

Reassess Periodically

DEXA

T score > -1.0
Z score > -2.0

Osteopenia (FRAX Score +)

OR

Osteoporosis (T-Score ≤ -2.5)

Bisphosphonate

Denosumab
Teriparatide

Other