Osteoporosis and Fracture Prevention

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Disclosures
Consultant and Speaker: Hologic
Advisory Board: LabCorp

Objectives
1. Discuss the diagnosis of osteoporosis and low bone mass
   – Bone density testing
   – FRAX
2. Discuss the role of non-pharmacologic agents in the prevention of bone fracture
   – Calcium
   – Vitamin D: treating deficiency and insufficiency
   – Fall prevention

Objectives
3. Discuss the pharmacologic treatment of low bone mass and osteoporosis
   1. Bisphosphonate therapy including oral and infusion
   2. SERMS
   3. PTH
   4. Rank Ligand Inhibitors
4. Discuss the current controversies in management of osteoporosis
   1. Long term use of bisphosphonates
   2. Osteonecrosis of the jaw (ONJ)
   3. Atypical subtrochanteric fractures of the femur

Osteoporosis Overview

Osteoporosis: Definition

A disease characterized by low bone mass and microarchitectural deterioration of bone tissue leading to enhanced bone fragility and a consequent increase in fracture risk

A Gender Related Condition

- Osteoporosis is the most common bone disorder affecting humans
- The risk of hip fracture doubles for every 5- to 6-year increase in age from ages 65-85
- Of the 10 million Americans estimated to have osteoporosis, 8 million are women (80%)

Vertebral Fractures

Significant consequences for patients

- Acute and chronic pain
- Kyphosis and height loss
- Impaired function
- Increased morbidity and mortality
- Increased fracture risk

Hip and Other Non-Vertebral Fractures Have Significant Consequences

- Hip fracture associated with
  - Loss of ambulatory status in 30% of patients
  - Increased morbidity and mortality
  - Increased fracture risk
  - Major reason for admission to chronic care facilities
- Non-vertebral fractures
  - Pain
  - Increased risk of future fractures

Fewer Than 35% of Hip Fracture Patients Receive Pharmacologic Treatment Within 6 Months

Fracture Liaison Service (FLS)

- To identify and treat patients with a recent fragility fracture
- Has been show to be effective and save money
- Multidisciplinary system approach
- Identifies patients at or proximate, to the time they are treated at the hospital for fracture
- Provides easy access to osteoporosis care.

Fragility Fractures “BONE ATTACK”

Over age 40, when a trip or fall from a STANDING HEIGHT leads to FRACTURE

- Defines a bone strength problem
- Impacts future risk for subsequent fracture
  - Bone Density is 70%
  - Bone Quality is 30%
- BMD for 40 and older
- Need to consider therapy

Who Should Be Screened?

National Osteoporosis Foundation (NOF) recommends screening for:

- Women aged 265 years and men aged ≥70 years, regardless of risk factors
  - Postmenopausal and menopausal transitioning women and men aged 50 to 69 years with clinical risk factors for fracture
  - Postmenopausal women and men aged ≥50 years who have had an adult-age fracture
  - Adults with a condition or taking a medication associated with low bone mass or bone loss

Dual-energy x-ray absorptiometry (DXA) is the current standard for measuring bone mineral density (BMD)
Who Should Be Screened?

North American Menopause Society (NAMS):¹
- All women ≥65 years, regardless of clinical risk factors
- Postmenopausal women with medical causes of bone loss
- Postmenopausal women ≥50 years with additional risk factors
- Postmenopausal women with a fragility fracture

US Preventive Services Task Force (USPSTF):
- Recommendations currently under review

What Are the Risk Factors?

Most common risk factors:¹,²,³
- Postmenopausal
- Female
- Low body mass index (BMI)
- Caucasian
- Poor calcium intake
- Lifestyle (eg, smoking, caffeine consumption >300 mg/d)

Other Risk Factors

Chronic medical conditions also increase risk and include:¹,²,³
- Chronic kidney disease
- Oral glucocorticoids (≥5 mg/d of prednisone for >3 months)
- Estrogen deficiency
- Hyperparathyroidism
- Systemic lupus erythematosus
- Conditions associated with malabsorption (eg, celiac disease, inflammatory bowel disease)
- Chronic obstructive pulmonary disorder

Medications and Osteoporosis Risk

> Corticosteroids
> Anticonvulsants
> Anticoagulants
> Immunosuppressive drugs
> Levothyroxine
> Lithium
> Heparin

Interpreting Bone Densitometry Results

Bone Density
FRAX: 10-Year Fracture Risk Calculation

T-Score Classifications

Using FRAX

To find those individuals at high risk for fracture, who are not yet osteoporotic!

If your patient has osteoporosis by T-score, you do not have to look at FRAX. BUT, you may look at FRAX!

More fractures occur in men and women with T-scores from -1.0 to -2.5!

FRAX: Gauging 10 Year Fracture Probability

Application of FRAX™ In the US

> Intended for post-menopausal women and men age 50 and older
> Has not been validated in patients currently or previously treated with pharmacotherapy for osteoporosis. In such patients, clinical judgment must be exercised in interpreting FRAX scores.
  - Patients who have been off osteoporosis medication for 1 to 2 years or more might be considered untreated.

Application of FRAX™ In the US

> Frax can be calculated with either femoral neck BMD or total hip BMD, but, when available, femoral neck BMD is preferred. Use of BMD from non hip sites is not recommended.
> T-scores must be converted to a reference standard to be used. The FRAX patch is available at [www.NOF.org](http://www.NOF.org) to make the calculation
> FRAX may be calculated by going to the FRAX calculator at the University of Sheffield website

Clinicians Guide to Prevention and Treatment of Osteoporosis
National Osteoporosis Foundation 2013

Application of FRAX™ In the US

The use of FRAX™ is for clinical guidance only and is not a rule.

Consider intervention strategies for those:
  - Who do not have osteoporosis by BMD
  - Do not meet the cut points after FRAX
  - Are not high enough risk of fracture despite low BMD

Conversely, the recommendations do not mandate treatment

Make decisions to treat on a case-by-case basis.

Clinicians Guide to Prevention and Treatment of Osteoporosis
National Osteoporosis Foundation 2014
Who Should Be Treated?

NOF recommends treating the following:
- Patients with osteopenia or low bone mass with a history of fragility fracture of the hip or spine
- Patients with a T-score of −2.5 or lower in the spine, femoral neck, total hip, or 1/3 of radius
- Patients with a T-score between −1.0 and −2.5 if the FRAX 10-year risk for major osteoporotic fracture is ≥20% or if the 10-year risk of hip fracture is ≥3%

Clinical Case

A 79-year-old Caucasian female presents for an osteoporosis risk evaluation. She has no medical problems, no history of fracture, and no family history of fracture. Her history is negative for smoking, glucocorticoid use, and excessive alcohol consumption.

Exam: weight, 154 lb; height, 64 in

DXA results:
- Femoral neck BMD (g/cm²), 0.730
- GE Lunar T-score: spine, −1.5; hip, −2.2
- FRAX 10-year risk of fracture: Major osteoporotic, 17%; hip, 5.2%

Based on this information:
- Does she require treatment due to osteoporosis?
- Is she at risk for a major fracture in the next 10 years?
- Is a discussion of preventive treatment indicated?

Clinical Case #1 (Cont)

Treatment

When and How

Non-Pharmacologic Interventions

> Goal of non-pharmacologic intervention is to prevent future fractures through lifestyle change
> The role of Vitamin D in osteoporosis
  - May be important as both adjuvant and treatment
  - Might be important in the response to therapy
  - The effect on muscle strength, balance and risk of falls is important
> Exercise
> Fall Prevention
**NOF Guidelines: When to Treat**

**Pharmacologic Treatment**
- Postmenopausal women or men over age 50 with a prior hip or spine fracture
- Postmenopausal women or men over 50 with a BMD T-score of -2.5 or lower at the hip or spine
- Postmenopausal women or men over 50 with T-score between -1 and -2.5 at the femoral neck, total hip, or spine if:
  - 10 year probability (from FRAX) of hip fracture ≥ 3%
  - 10 year probability of a major osteoporosis-related fracture ≥ 20%

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**Treatment Recommendations**

- No pharmacologic therapy should be considered indefinite in duration
- After the initial three to five year treatment period, a comprehensive risk assessment should be performed
- There is no uniform recommendation that applies to all patients and duration decisions need to be individualized

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**Current Pharmacologic Agents Approved for the Treatment of Osteoporosis**

**Anti-resorptive agents**
- Bisphosphonates
  - Weekly oral alendronate (Fosamax)
  - Weekly or monthly risedronate (Actonel)
  - Monthly oral or quarterly IV ibandronate (Boniva)
  - Once yearly infusion Zoledronic Acid (Reclast)
- Rank Ligand Inhibitor
  - Denosumab (Prolia)

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**Current Pharmacologic Agents Approved for the Treatment of Osteoporosis**

- Calcitonin
- Selective estrogen receptor modulators (SERMS)
  - Raloxifene (Evista)
- Anabolic agents
  - Parathyroid hormone (Forteo)
  - Abaloparatide (Tymlos)

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**Anti-resorptive Therapy**

Bisphosphonates
Rank Ligand Inhibitors
SERMS
Calcitonin

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**Osteoporosis Treatment**

Bisphosphonates
Effects of Bisphosphonates

- Decreased bone turnover
- Increased BMD at spine and hip
- Decreased risk of vertebral and hip fractures
- Sustained effects with continued treatment
- Best studied class of agents used in treating osteoporosis
- Long term safety record


Bisphosphonates

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mechanism of action</th>
<th>Prevention dose</th>
<th>Treatment dose</th>
<th>Fracture risk reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate</td>
<td>Anti-resorptive agents that inhibit osteoclast function</td>
<td>5 mg/day or 20 mg/week</td>
<td>10 mg/day or 70 mg/week</td>
<td>Some, hip, non-vertebral</td>
</tr>
<tr>
<td>Ibandronate</td>
<td>Anti-resorptive agents that inhibit osteoclast function</td>
<td>2.5 mg/day or 150 mg/month</td>
<td>2.5 mg/day, 150 mg/month, or 3 mg every 3 mo</td>
<td>Vertebral</td>
</tr>
<tr>
<td>Risedronate</td>
<td>Anti-resorptive agents that inhibit osteoclast function</td>
<td>5 mg/day, 35 mg/week, or 150 mg/month</td>
<td>5 mg/day, 35 mg/week, or 150 mg/month</td>
<td>Some, hip, non-vertebral</td>
</tr>
<tr>
<td>Zoledronic acid</td>
<td>Anti-resorptive agents that inhibit osteoclast function</td>
<td>5 mg every second year</td>
<td>5 mg/year</td>
<td>Some, hip, non-vertebral</td>
</tr>
</tbody>
</table>


ORAL BISPHOSPHONATES

Pros
- Osteoporosis prevention and treatment
- Reduction in risk of vertebral fractures (w/ and w/o pre-existing fx)

Cons
- Require lifestyle change
  - empty stomach
  - water only
  - may lead to non-compliance
- GI adverse effects
- Marginal efficacy in non-vertebral fractures (e.g. hip)
- Long-term safety is unconfirmed


Absorption and Tolerability of Oral Bisphosphonates Are Affected When Dosing Instructions are not Followed

- Coffee or juice can reduce absorption by as much as 60%
- Calcium supplements can interfere with absorption and should not be taken at the same time as oral bisphosphonate therapy
- GI side effects are more likely when dosing instructions are not followed
- Even when complete instructions are given, between 25% and 50% of patients disregard at least one requirement


IV Bisphosphonate

Zoledronic Acid

HORIZON Fracture Trials: Efficacy Conclusions
- Reduces incidence of vertebral fractures by 70% (with significant reduction at 1 year)
- Reduces hip fractures by 41%
- Reduces nonvertebral fractures by 25%, over 3 years in patients with osteoporosis, defined by prevalent vertebral fractures and osteoporosis by BMD of the hip

Bioavailability and High Binding Affinity Allow Zoledronic Acid to be Dosed Once Yearly

- Zoledronic acid bypasses the GI tract, eliminating absorption limitations
- Year long efficacy of zoledronic acid is attributable to the high binding affinity of zoledronic acid to bone
- Bioavailability:
  - approximately 61% directly to bone
  - Approximately 39% eliminated from circulation within 24 hours

Zoledronic acid (prescribing information) East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2008

Antiresorptive Agents Beyond Bisphosphonates

Denosumab

RANK Ligand Inhibitor
- Fully human monoclonal antibody
- Specifically targets a ligand called RANKL (that binds to a receptor called RANK) which is a key mediator of:
  - Osteoclast formation
  - Function
  - Survival
- Improves cortical and trabecular bone density, volume and strength
- Currently being studied across a range of conditions including osteoporosis, treatment induced bone loss, bone metastases, multiple myeloma and rheumatoid arthritis

Discontinuation of Denosumab Therapy
- Denosumab discontinuation may lead to an increased risk of multiple vertebral fractures.
- Re-evaluation should be performed after 5 years of denosumab treatment.
- Patients considered at high fracture risk should either:
  - Continue denosumab therapy for up to 10 years
  - Or be switched to an alternative treatment.

New Agent: Romosozumab

Not yet FDA approved:
- Monoclonal antibody that binds sclerostin
  - Increases bone formation
  - Decreases bone resorption
  - Rapid onset of fracture reduction, in the first 6 months
- Adverse events were balanced in the 12 and 24 month studies between placebo and treatment groups
- One atypical fracture and 2 cases of osteonecrosis of the jaw in the treatment group

Effects of SERMS (Estrogen agonist/antagonists)

- SERMS exert estrogen-like effects on the skeleton
- Decrease bone turnover
- Increase bone density, but to a lesser degree than with bisphosphonates
- Decrease risk of vertebral fracture
- No hip or non-vertebral fracture


Raloxifene

- **Pros**
  - Osteoporosis prevention
  - No endometrial or breast stimulation
  - LDL reduction

- **Cons**
  - No current non-vertebral fracture data (e.g. hip)
  - No effect on vasomotor symptoms
  - Thrombosis
  - Effects on cholesterol are modest
  - Leg cramps


Anabolic Agents

- Unique from other treatments because they are bone building through increased osteoblast activity
- Effects diminish quickly after discontinuing therapy
- Teriparatide
  - Increases BMD up to 13% at spine and to a lesser degree at hip
  - Correlates to 72% relative risk reduction of new vertebral fractures
- Abaloparatide
  - Increases BMD at all sites
  - Relative risk reduction of 86% for new vertebral fractures and 43% for nonvertebral fractures


Effects of Parathyroid Hormone

- Stimulates osteoblast activity preferentially
- Increases bone turnover and creates a positive bone balance
- Improves trabecular microarchitecture and increases cortical thickness
- Increases bone mass
- Decreases risk of vertebral and nonvertebral fractures
- Requires daily injections


Parathyroid Hormone

- **Pros**
  - Osteoporosis treatment
  - Reduction in risk of vertebral and nonvertebral fractures
  - May be used in conjunction with other OP therapies (e.g. anti-resorptive)

- **Cons**
  - Osteosarcoma risk?
  - Long-term use not established
  - Long-term safety not established
  - Hip fracture prevention?
  - Daily sq injections
  - Nausea, headache, etc.


Teraparatide

- FDA approved 2002
- Recombinant human parathyroid hormone analog (1-34), [rhPTH(1-34)] indicated for:
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture
  - Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
  - Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Self-administered subcutaneous injection for 2 years followed by bisphosphonate therapy
- Carries a label warning regarding osteosarcoma
Abaloparatide
FDA approved 4/28/17

- Indicated for:
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture defined as:
    - A history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
  - Lab-made copy of part of the human parathyroid hormone-related protein (PTHrP)
  - Daily subcutaneous injection
  - Recommended for two years and followed with bisphosphonates for several years
  - Carries a label warning regarding osteosarcoma
  - Side effects include nausea, dizziness, and vomiting

Hormone Therapy
Estrogen Therapy
Approved for prevention only

Hormone Replacement Therapy
(HRT, Estrogen)

- Pros
  - Osteoporosis prevention
  - Cognitive benefits (?)
  - Urogenital symptom improvement

- Cons
  - Withdrawal bleeding
  - Endometrial cancer with unopposed estrogen
  - Breast cancer
  - Heart attack
  - Stroke
  - Thrombosis

American College of Physicians Recommendations

<table>
<thead>
<tr>
<th>Drug</th>
<th>Length of use</th>
<th>BMD monitoring during treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-line therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alendronate, risedronate, zoledronic acid, denosumab</td>
<td>5 y</td>
<td>Yes</td>
</tr>
<tr>
<td>Second-line therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibandronate, raloxifene</td>
<td>Individually to patient</td>
<td></td>
</tr>
</tbody>
</table>

- Recommend against the use of raloxifene or menopausal hormone therapy to treat osteoporosis
- Omitted anabolic agents from recommendations

American Association of Clinical Endocrinologists and American College of Endocrinology Recommendations

<table>
<thead>
<tr>
<th>Drug</th>
<th>Length of use</th>
<th>BMD monitoring during treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-line therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biphosphonates: High risk, 10 y Low risk, consider drug holiday after 5 y Every 1.2 y until BMD is stable or individualized to risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second-line therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anabolic agent teriparatide</td>
<td>2 y</td>
<td></td>
</tr>
</tbody>
</table>

- Raloxifene or menopausal hormone therapy may be a reasonable option in select patients

Addressing Recent Controversies in the Treatment of Osteoporosis
Addressing Recent Controversies

> Long term use of bisphosphonate therapy
> Bisphosphonate therapy and the occurrence of fractures of the subtrochanteric or diaphyseal femur
> Osteonecrosis of the jaw (ONJ)

Bisphosphonates

> Concerning adverse effects:
  • Osteonecrosis of the jaw
    - Risk 1:1,000 to 1:263,000
    - Not associated with treatment duration
    - Potential risk factors include poor oral hygiene, glucocorticoid therapy, and chemotherapy
  • Atypical femur fractures
    - Risk increases with longer therapy duration
    - Subtrochanteric and diaphyseal femoral fractures
> Bisphosphonates accumulate in the bone, so drug holidays are recommended to reduce long-term risk

Addressing Recent Controversies

> Treatment decisions require risk and benefit discussions
> What was acceptable risk previously, may no longer be acceptable
> If disease state risk is high: fracture
  - Risk of rare complications may be outweighed

Addressing Recent Controversies

Long term use of bisphosphonate therapy:

> Bisphosphonate therapy and the occurrence of fractures of the subtrochanteric or diaphyseal femur
> Osteonecrosis of the jaw (ONJ)

Long-Term Use of Bisphosphonates

New guidance: American Society for Bone and Mineral Research (ASBMR):
  - Long-term treatment with medications reduces the likelihood of fractures in women at high risk
  - Reassess for risk after 5 years of oral treatment and after 3 years of IV treatment
  - Women at high risk for fractures should continue oral treatment up to 10 years and IV treatment up to 6 years with intermittent follow-up
  - Women whose risk of fractures decreases after 3 to 5 years should stop treatment and be reassessed every 2 to 3 years
  - If have fracture during treatment continue bisphosphonate or switch to alternative therapy and reassess every 2 to 3 years

Use of Drug Holidays in Women Taking Bisphosphonates

NAMS Practice Pearl
> Bisphosphonates are generally safe and well-tolerated
> For most patients at moderate or high risk: benefits of treatment far outweigh the RARE risks
> It is reasonable to consider a “drug holiday” from bisphosphonate therapy
> The duration and length of the holiday should be based on clinical judgment

Individualize based on risk/benefit assessments

Fractures of the Subtrochanteric or Diaphyseal Femur

FDA Safety Communication - 3/10/2010
> Reports out of the American Academy of Orthopedic Surgeons:
  - Is an increased risk of a rare femur fracture in patients with osteoporosis using bisphosphonates?
> At this point, the data that FDA has reviewed:
  - Have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures.

National Osteoporosis Foundation (NOF) Position Statement for Patients
> Based on information that is currently available, NOF believes that for most people taking bisphosphonate medicines, the benefits outweigh the risks of these unusual, but serious conditions that appear to be associated with them.

Osteonecrosis of the Jaw (ONJ)
> Jaw lesions, usually after dental extraction have been observed with bisphosphonate use
  - Most often in patients treated with large IV doses for cancer-related bone diseases.
> ONJ has been defined as a delay in healing of an oral lesion after surgery or extraction for more than 6 to 8 weeks.


Drug Holiday Recommendations

<table>
<thead>
<tr>
<th>Risk level for fracture</th>
<th>Initiate drug holiday</th>
<th>Therapy during holiday</th>
<th>Length of holiday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>After 5 y of stability on oral treatment or after 3 y with intravenous zoledronic acid</td>
<td>None</td>
<td>Individual to patient risk</td>
</tr>
<tr>
<td>High risk and remains at high risk</td>
<td>After 10 y of oral therapy or after 5 y for intravenous zoledronic acid</td>
<td>Consider teriparatide or raloxifene</td>
<td>Individual to patient risk</td>
</tr>
</tbody>
</table>


Summary
> Osteoporosis is under diagnosed and preventative care is under utilized
> Current practice requires dialogue between patient and practitioner in regards to individual risk and risk and benefits of therapeutic options
> Treatment strategies must be individualized to obtain greater compliance to therapy
> Practitioners will need to stay current while treatment recommendations continue to be reviewed and possibly changed
Cases

BMD
FRAX

The Art of Managing Osteoporosis and Fracture Prevention!

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Case #1

> 72 year old Caucasian woman
> Non-smoker
> F.H. Osteoporosis in Mother
> Negative for secondary causes of osteoporosis

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Case #2

> 52 year old Caucasian
> Non-smoker
> Negative for secondary causes of Osteoporosis
Case #3

82 yo woman
LS: normal with -0.9
Hip: Moderate low bone mass (Osteopenia) -2.0

Patient has never been treated with pharmacologic therapy. She denies problem with swallowing, GERD or known esophagus problem. She has mild CKD and is being followed by a nephrologist.

Would you treat this patient?
What would you prescribe?
Case #4

84 yo on long term oral bisphosphonate therapy for over 10 years.
BMD:
LS: Severe osteoporosis T score -4.6
Hip: Severe osteoporosis T score -3.7

I referred the patient to the endocrinologist for an opinion.

Have you ever seen a FRAX this high??
What are the options for treating this patient?

Case #4

> What would you recommend for this patient who has been on long term bisphosphonate therapy?
> She is at very high risk for fracture!!

> What are your options?
> What did the endocrinologist recommend?

Case #5

> 63 yo woman has a family history of breast cancer in her Mother.
> Bone density test
  – LS: T-score -2.4
  – Hip: -1.6 at femoral neck
> Does she have osteoporosis?
> Is it important to look at her FRAX score?
> What are her options for therapy?

Case #5

> Pt prefers to take Raloxifene and starts the medication
> What risk factors are important to identify for this patient?
> The patient has her bone density repeated in 2 years and stays on her Raloxifene
> 2 years later her BMD shows a T score of -2.5 in the femoral neck
> What will you do about her treatment plan?
> Will she stay on Raloxifene?
Case #6

85 yo woman
BMD shows:
LS: Mild low bone mass with T score of -1.4
Hip: Osteoporosis with T score of -2.8

Patient has been on oral bisphosphonate therapy for 8 years and is not having any problem.

Long Term Use of Oral Bisphosphonate

> Would you continue her therapy?
> Is she at high risk for fracture?

> Would her FRAX calculation make any difference in your treatment decision?
> Is the FRAX calculation always correct when based on the patient answers to the questionnaire?

FRAX is only as accurate as the information that is entered. Recalculation can be done if there is any question.

National Osteoporosis Foundation
Bibliography


Bibliography