Osteoporosis - Breaking News!

SCS Annual Osteopathic OBGYN Review Course
April 2, 2019
Director of the Beaumont Endocrine Center
Chief of Endocrinology: William Beaumont Hospital Grosse Pointe
A 42-year-old woman is evaluated in the office for osteoporosis because she was told her heel ultrasound screening test was abnormal at a health fair. She has no history of fractures. Family history is significant for osteoporosis in her mother, diagnosed at age 68 years; she has no history of fracture. Her only medication is a combination estradiol-levonorgestrel oral contraceptive pill.

On physical examination, vital signs are normal. BMI is 19. The remainder of her physical examination is normal.

Report of the quantitative heel ultrasound shows a Z-score of −0.5.

Which of the following is the most appropriate management?

- A) Lifestyle counseling for osteoporosis prevention
- B) Dual-energy x-ray absorptiometry (DEXA) scan
- C) Evaluation of secondary causes of bone loss
- D) Serial quantitative heel ultrasound testing
A 72-year-old woman is evaluated in follow-up for osteoporosis. Medical history is significant for a hip fracture 5 years ago sustained after a mild fall. Evaluation at that time included a dual-energy x-ray absorptiometry (DEXA) scan showing a left hip T-score of −2.8 and vertebral T-score of −2.7. She has been maintained on alendronate therapy since that time. Medical history is also significant for hypertension. Medications are alendronate, hydrochlorothiazide, calcium, and vitamin D. Family history is significant for osteoporosis in her mother, sister, and maternal aunt. She has a 35-pack-year tobacco use history and continues to smoke.

On physical examination, temperature is 36.9 °C (98.4 °F), blood pressure is 138/87 mm Hg, pulse rate is 89/min, and respiration rate is 12/min. BMI is 28. She has marked thoracic kyphosis and increased central adiposity.

Laboratory studies show a serum calcium level of 8.6 mg/dL (2.2 mmol/L) and 25-hydroxyvitamin D level of 44 ng/mL (109.8 nmol/L); kidney function studies are normal.

Repeat DEXA shows a stable bone mineral density.

Which of the following is the most appropriate treatment of this patient's osteoporosis?

A. Change to denosumab
B. Change to teriparatide
C. Continue alendronate therapy
D. Initiate a drug holiday
A 74-year-old woman is evaluated for back pain after a fall occurring 2 weeks ago. Medical history is significant for deep venous thrombosis 3 years ago following a 12-hour airplane flight. Medications are acetaminophen as needed for back pain and calcium carbonate with vitamin D.

On physical examination, vital signs are normal. She has minimal pain to percussion over T8. Her examination is otherwise normal.

**Laboratory studies:**

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Lateral spine radiograph shows 30% compression of T8, not present on prior radiographs. Bone mineral density by DEXA shows a lumbar spine T-score of −3.0 and femur neck T-score of −2.8.

**Which of the following is the most appropriate treatment?**

- [ ] A Alendronate
- [ ] B Calcitonin
- [ ] C Denosumab
- [ ] D Raloxifene
- [ ] E Teriparatide
A 63-year-old woman was diagnosed with osteoporosis 6 years ago. Initial treatment with an oral bisphosphonate resulted in upper gastrointestinal symptoms, so subcutaneous denosumab twice yearly was prescribed. The patient has now completed 5 years of denosumab therapy. Medical history is otherwise unremarkable. Denosumab was last administered 6 months ago.

Vital signs and the remainder of the physical examination are normal.

Which of the following is the most appropriate management?

A. Continue denosumab
B. Dual-energy x-ray absorptiometry (DEXA) scan
C. Osteoporosis drug holiday
D. Switch to zoledronic acid
A 54-year-old woman comes to the office for advice regarding maintaining bone health. She has no history of fracture. The patient recently had a lumpectomy and radiation therapy to treat breast cancer, is currently taking tamoxifen, and will begin taking an aromatase inhibitor in 2 months. She underwent menopause at age 52 years and has persistent hot flushes. Her risk factors for osteoporosis include a slim body habitus and a mother who had a hip fracture at age 67 years.

Physical examination findings, including vital signs, are normal. BMI is 20.

Results of routine laboratory studies are normal.

A dual-energy x-ray absorptiometry scan shows T-scores of −2.1 in the lumbar spine, −2.3 in the femoral neck, and −1.9 in the total hip. Her Fracture Risk Assessment Tool (FRAX) score indicates a 22% risk of major osteoporotic fracture and a 2.4% risk of hip fracture over the next 10 years. Optimal calcium and vitamin D supplementation is recommended, and she is encouraged to begin weight-bearing exercise as tolerated.

Which of the following pharmacologic agents can be started in this patient?

A  Alendronate  
B  Denosumab  
C  Estrogen  
D  Raloxifene  
E  Teriparatide
A 66-year-old woman comes to the office for management of osteoporosis discovered on a screening dual-energy x-ray absorptiometry (DEXA) scan. The patient has no personal history of fractures and no family history of parathyroid disease or low bone mineral density. She has hypertension treated with lisinopril but takes no other medications or supplements.

On physical examination, vital signs are normal; BMI is 22. Dentition is good. Other than mild kyphosis, physical examination findings are unremarkable.

**Laboratory studies:**

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<td>Albumin</td>
<td>4.0 g/dL (40 g/L)</td>
</tr>
<tr>
<td>Calcium</td>
<td>8.7 mg/dL (2.2 mmol/L)</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.7 mg/dL (61.9 μmol/L)</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>2.9 mg/dL (0.94 mmol/L)</td>
</tr>
<tr>
<td>Parathyroid hormone</td>
<td>176 pg/mL (176 ng/L)</td>
</tr>
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</table>

The DEXA scan showed T-scores of −2.1 in the lumbar spine, −3.0 in the femoral neck, and −2.5 in the total hip. Radiographs of the lateral spine show no compression fractures.

Which of the following is the most appropriate next step in management?

- [A] Measurement of 1,25-dihydroxyvitamin D level
- [B] Measurement of 25-hydroxyvitamin D level
- [C] Parathyroidectomy
- [D] Repeat DEXA scan in 1 year
Conflict

- I’m married to a drug representative and she works for Amgen
  - Makers of Denosumab

- I’m an expert on insulin pumps and continuous glucose monitors lead groups for the Valeritas and Dexcom Corporation
Objectives

- To define osteoporosis
- To determine who we should treat based on evidence based medicine and clinical criteria
- Understand the available treatments for osteoporosis
- Try to obtain a proper duration of therapy and end point
Resources

- National Osteoporosis Foundation
- American Academy of Clinical Endocrinologists
- United States Preventative Task Force
- Endocrine Society
Main Resources
Burden of Osteoporosis

- Osteoporosis is a silent disease until it is complicated by fractures
- These fractures are common, and place an enormous medical and personal burden on aging individuals. It also places a major economic toll on the nation
Burden of Osteoporosis

**Fig. 3.** Comparative incidences of osteoporosis-related fractures, new strokes, heart attacks, and invasive breast cancer in women in the United States, based on recent statistics (2004 to 2006). Data from Burge et al (11), Rosamond et al (American Heart Association Statistics Committee and Stroke Statistics Subcommittee) (12), and American Cancer Society (13).
Defining Osteoporosis

- Characterized by:
  - Low bone mass
  - Deterioration of bone tissue/architecture
  - Compromised bone strength
  - Increase in the risk of fracture
Osteoporosis

FIGURE 1. Micrographs of Normal vs. Osteoporotic Bone

Normal bone

Osteoporotic bone

From: Dempster, DW et al.6, with permission of the American Society for Bone and Mineral Research.

CLINICIAN'S GUIDE TO PREVENTION AND TREATMENT OF OSTEOPOROSIS © 01/2010
Consider Osteoporosis Risks in…

- All women and men age 50 and older
  - Low BMI
  - Current Smoker
  - History of rheumatoid arthritis
  - Glucocorticoid exposure
  - Parent hip fracture
  - Alcohol > 3 drinks per day
  - Secondary Osteoporosis
**Table 9**

**Some Causes of Secondary Osteoporosis in Adults**

<table>
<thead>
<tr>
<th>Endocrine or metabolic causes</th>
<th>Nutritional/gastrointestinal conditions</th>
<th>Drugs</th>
<th>Disorders of collagen metabolism</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acromegaly</td>
<td>Alcoholism</td>
<td>Antiepileptics&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Ehlers-Danlos syndrome</td>
<td>AIDS/HIV</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Anorexia nervosa</td>
<td>Aromatase inhibitors</td>
<td>Homocystinuria due to cystathionine deficiency</td>
<td>Ankylosing spondylitis</td>
</tr>
<tr>
<td>Type 1</td>
<td>Calcium deficiency</td>
<td>Chemotherapy/immunosuppressants</td>
<td>Marfan syndrome</td>
<td>Chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>Type 2</td>
<td>Chronic liver disease</td>
<td>Depo-Provera</td>
<td>Osteogenesis imperfecta</td>
<td>Gaucher disease</td>
</tr>
<tr>
<td>Growth hormone deficiency</td>
<td>Malabsorption syndromes/ malnutrition (including celiac disease, Crohn disease, and gastric resection or bypass)</td>
<td>Lithium</td>
<td></td>
<td>Hemophilia</td>
</tr>
<tr>
<td>Hypercortisolism</td>
<td></td>
<td>Glucocorticoids</td>
<td>Gonadotropin-releasing hormone agonists</td>
<td>Hypercalciuria</td>
</tr>
<tr>
<td>Hyperparathyroidism</td>
<td></td>
<td></td>
<td>Heparin</td>
<td>Immobilization</td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td></td>
<td></td>
<td>Lithium</td>
<td>Major depression</td>
</tr>
<tr>
<td>Hypogonadism</td>
<td></td>
<td></td>
<td>Proton pump inhibitors</td>
<td>Myeloma and some cancers</td>
</tr>
<tr>
<td>Hypophosphatasia</td>
<td></td>
<td></td>
<td>Selective serotonin reuptake inhibitors</td>
<td>Organ transplantation</td>
</tr>
<tr>
<td>Porphyria</td>
<td>Vitamin D deficiency</td>
<td>Thiazolidinediones</td>
<td>Thyroid hormone (in supraphysiologic doses)</td>
<td>Renal insufficiency/failure</td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
<td></td>
<td>Warfarin</td>
<td>Renal tubular acidosis</td>
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<sup>a</sup> AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus.

<sup>b</sup> Phenobarbital, phenytoin, primidone, valproate, and carbamazepine have been associated with low bone mass.
How to Assess Osteoporosis

- Bone Mineral Density (BMD)
- Fracture Risk Assessment Model
- Imaging
- Clinical decision making and lab assessments
- Bone biopsy
Who gets BMD testing?

- Women and men age 50 and older with increased risk
- Women age 65 and older (USPSTF Rec)
- Men age 70 and older, regardless of clinical risk factors (NOF, AACE, and Endocrine Society endorsed)
NO BMD t-scores in patient <50yo

- In premenopausal women, men less than 50 years of age and children, the WHO BMD diagnostic classification should not be applied.
Bone Mineral Density (BMD)

**T-score**

- Compares an individual's BMD to the expected BMD of "young normal" adults (approximately 25 years old) of the same sex

- The difference between the patient’s score and the norm is expressed in standard deviations (SD) above or below the mean
### T-Score

<table>
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<tr>
<th>Category</th>
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</tr>
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<tbody>
<tr>
<td>Normal</td>
<td>-1.0 or above</td>
</tr>
<tr>
<td>Low bone mass (osteopenia)(^a)</td>
<td>Between -1.0 and -2.5</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>-2.5 or below</td>
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\(^a\) Fracture rates within this category vary widely. The category of "osteopenia" is useful for epidemiology studies and clinical research but is problematic when applied to individual patients and must be combined with clinical information to make treatment decisions.
Z-score

- Compares an individual’s BMD to the expected BMD for the patient’s peers based on age and sex.

- The difference between the patient’s score and the norm is expressed in standard deviations (SD) above or below the mean.
T-score and Z-score

- T-scores to define a diagnosis
- Z-scores suggest a secondary cause of osteoporosis
# Low Bone Mass, a.k.a. Osteopenia

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*a Fracture rates within this category vary widely. The category of “osteopenia” is useful for epidemiology studies and clinical research but is problematic when applied to individual patients and must be combined with clinical information to make treatment decisions.*
What to do with low bone mass (osteopenia)?

- FRAX it!
Fracture Risk Assessment Model (FRAX)

- FRAX® was developed to calculate the 10-year probability of a hip fracture and major osteoporotic fracture (defined as clinical vertebral, hip, forearm or proximal humerus fracture) taking into account clinical risk factors.
Fracture Risk Assessment Model (FRAX)

- Apply FRAX calculation to any patient with low bone mass (Osteopenia)

- Do NOT apply FRAX with,
  - Women and men age less than 50
  - Patients currently/previous treated for osteoporosis
FRAX Indicates Treatment When

- Major osteoporosis-related fracture probability ≥ 20%
- Hip fracture probability ≥ 3%
http://www.shef.ac.uk/FRAX/
Patient Example

T = -2.3, wt = 150#, No Risks
Patient Example
T = -2.3, wt=150#, With Risks
If Fractured, then Osteoporosis
Pharmacological Treatment for the Following:

- T-score ≤ -2.5 at the femoral neck or spine after appropriate evaluation to exclude secondary causes

- Low bone mass (T-score between -1.0 and -2.5 at the femoral neck or spine) and a 10-year probability of a hip fracture ≥ 3% or a 10-year probability of a major osteoporosis-related fracture ≥ 20% based on the US-adapted WHO algorithm

- A hip or vertebral (clinical or morphometric) fracture
Pharmacological Classes

- Calcitonin
- Estrogen – prevents, does NOT treat
- Selective Estrogen receptor modifiers (SERM)
- Receptor activator of nuclear factor κB (RANK) ligand inhibitor
- Bisphosphonates
- Recombinant human PTH
- Sclerostin inhibitors
Denosumab (Prolia)

- Leads to decreased osteoclastogenesis
Denosumab (Prolia)

- Administered by injection every 6 months
- Fracture prevention is comparable to bisphosphonate therapy
- Osteonecrosis of the jaw has been reported
- No known kidney metabolism issues (Can be used in patients with low GFR)
- Caveat – Once started effect wanes and bone loss resumes after 6-9 months; therefore it becomes a LIFE LONG therapy
Bisphosphonates

- Bisphosphonates bind to the bone matrix and decrease osteoclast activity.
Bisphosphonates

- Patient should be upright for 30 minutes after taking with water only and on an empty stomach

- Intravenous bisphosphonates, e.g. Zoldronic acid (Reclast), is available for patients with esophagitis, active esophageal disease, or swallowing disorders
Bisphosphonates

- Not recommended for patients with
  - Impaired kidney function (creatinine clearance less than 30-35 mL/min)
Risk of Denosumab and Bisphosphonate Use

- Osteonecrosis of the jaw
- Atypical Fracture
Atypical Fracture

- A distinct type of fracture that occurs in the femur below the greater trochanter
- Has been associated with a long duration of antiresorptive therapy
- No study has proven the association to be causal
Radiographs of patients diagnosed with atypical femoral fractures.


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Duration of Treatment with Bisphosphonates

- Antiresorptive therapy should likely continue in very high risk people (previous hip fracture, high risk of fall, smoker, chronic glucocorticoid, family history of hip fracture, rheumatoid arthritis)
- Antiresorptive therapy with bisphosphonates should probably be stopped after 5-10 years for a duration in minimal risk individuals
- Typically physicians are now treating for 5-7 years, then stop for 2-5 years, and resume if needed
A 42-year-old woman is evaluated in the office for osteoporosis because she was told her heel ultrasound screening test was abnormal at a health fair. She has no history of fractures. Family history is significant for osteoporosis in her mother, diagnosed at age 68 years; she has no history of fracture. Her only medication is a combination estradiol-levonorgestrel oral contraceptive pill.

On physical examination, vital signs are normal. BMI is 19. The remainder of her physical examination is normal.

Report of the quantitative heel ultrasound shows a Z-score of −0.5.

Which of the following is the most appropriate management?

[A] Lifestyle counseling for osteoporosis prevention
[B] Dual-energy x-ray absorptiometry (DEXA) scan
[C] Evaluation of secondary causes of bone loss
[D] Serial quantitative heel ultrasound testing
Which of the following is the most appropriate management?

67%  A Lifestyle counseling for osteoporosis prevention
26%  B Dual-energy x-ray absorptiometry (DEXA) scan
  7%   C Evaluation of secondary causes of bone loss
  0%   D Serial quantitative heel ultrasound testing

Answer & Critique

Correct Answer: A

The most appropriate management for this patient is lifestyle counseling for osteoporosis prevention. Lifestyle measures include adequate calcium and vitamin D, exercise, smoking cessation, counseling on fall prevention, and avoidance of heavy alcohol use.

Most guidelines recommend screening for osteoporosis with dual-energy x-ray absorptiometry (DEXA) scan in women 65 years of age and older. Screening of younger women may be indicated if one or more risk factors for osteoporosis are present. In premenopausal women without risk factors, assessment of bone mineral density (BMD) for fracture risk is not advised or validated. However, if testing is done in an otherwise healthy person, such as this patient, results that are below age- and gender-matched averages (Z-score <0) generally do not require further evaluation or serial monitoring. The discovery of below average BMD could lead to a discussion regarding osteoporosis prevention with lifestyle modification and assessment of BMD after menopause, but prior to age 65, when screening might otherwise occur.

Testing for secondary causes of bone loss is unnecessary when BMD is normal for age. Below average BMD in adults may in fact represent below average peak bone mass rather than loss of bone.

Although BMD measured by quantitative heel ultrasound is predictive of osteoporotic fracture in older women and men, BMD measurement by DEXA scan remains the gold standard for diagnosis of osteoporosis and fracture risk assessment. Therefore, abnormal ultrasound results in these populations should be confirmed by DEXA scan. Even so, a DEXA scan should not be performed in this patient given that screening is not indicated and the heel ultrasound result is within the normal range.

Key Point

Screening for osteoporosis in premenopausal women is not indicated in the absence of risk factors.
A 72-year-old woman is evaluated in follow-up for osteoporosis. Medical history is significant for a hip fracture 5 years ago sustained after a mild fall. Evaluation at that time included a dual-energy x-ray absorptiometry (DEXA) scan showing a left hip T-score of −2.8 and vertebral T-score of −2.7. She has been maintained on alendronate therapy since that time. Medical history is also significant for hypertension. Medications are alendronate, hydrochlorothiazide, calcium, and vitamin D. Family history is significant for osteoporosis in her mother, sister, and maternal aunt. She has a 35-pack-year tobacco use history and continues to smoke.

On physical examination, temperature is 36.9 °C (98.4 °F), blood pressure is 138/87 mm Hg, pulse rate is 89/min, and respiration rate is 12/min. BMI is 28. She has marked thoracic kyphosis and increased central adiposity.

Laboratory studies show a serum calcium level of 8.6 mg/dL (2.2 mmol/L) and 25-hydroxyvitamin D level of 44 ng/mL (109.8 nmol/L); kidney function studies are normal.

Repeat DEXA shows a stable bone mineral density.

Which of the following is the most appropriate treatment of this patient's osteoporosis?

A. Change to denosumab
B. Change to teriparatide
C. Continue alendronate therapy
D. Initiate a drug holiday
Which of the following is the most appropriate treatment of this patient's osteoporosis?

- 10% A Change to denosumab
- 12% B Change to teriparatide
- 29% C Continue alendronate therapy
- 50% D Initiate a drug holiday

**Answer & Critique**

Correct Answer: C

**Educational Objective:** Treat a high-risk patient with osteoporosis.
Educational Objective: Treat a high-risk patient with osteoporosis.

After counseling about smoking cessation, this patient should continue her current alendronate therapy. She has documented osteoporosis and is at high risk for subsequent fractures due to multiple risk factors, including current smoking and a previous fracture. Her bone mineral density (BMD) has been well maintained on an oral bisphosphonate for the last several years. The best way to evaluate a dual-energy x-ray absorptiometry (DEXA) scan from measurement to measurement is to compare the bone mineral density readings from year to year, not the T-score. A change in BMD that is less than about 4% (or the percentage noted by the DEXA machine manufacturer) is not considered a statistically significant change. This regimen should be considered successful therapy since the goal of bisphosphonates is not to build bone mass but to stabilize bone loss. Since this patient has had stable BMD while on alendronate, there is no indication to convert to a more invasive, expensive option at this time. It will be important, however, to continue to follow her for atypical fractures of the long bone due to her prolonged bisphosphonate treatment. If leg pain or an atypical fracture is noted, bisphosphonate therapy should be discontinued.

Denosumab is a receptor activator of nuclear factor κB (RANK) ligand inhibitor FDA approved for the treatment of osteoporosis in postmenopausal women who are at high risk of fracture. Since this patient has not failed bisphosphonate therapy (shown a significant decrease in BMD while on bisphosphonate therapy) nor is she intolerant of the current therapy, there is no reason to change her therapy.

Teriparatide is appropriate as first-line therapy for patients at high risk for fracture (T-score < −3.0) or who have experienced progressive osteoporotic disease while on bisphosphonate therapy. This change would be unnecessary since the patient's BMD has been maintained for the past 5 years.

A drug holiday is indicated for patients who have been on bisphosphonate therapy for 3 to 5 years, have had no progression of the disease, and have minimal risk factors for additional fractures. This patient has multiple risk factors for fractures; therefore, a drug holiday would not be appropriate.
A 74-year-old woman is evaluated for back pain after a fall occurring 2 weeks ago. Medical history is significant for deep venous thrombosis 3 years ago following a 12-hour airplane flight. Medications are acetaminophen as needed for back pain and calcium carbonate with vitamin D.

On physical examination, vital signs are normal. She has minimal pain to percussion over T8. Her examination is otherwise normal.

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Lateral spine radiograph shows 30% compression of T8, not present on prior radiographs. Bone mineral density by DEXA shows a lumbar spine T-score of −3.0 and femur neck T-score of −2.8.

**Which of the following is the most appropriate treatment?**

- [ ] A. Alendronate
- [ ] B. Calcitonin
- [ ] C. Denosumab
- [ ] D. Raloxifene
- [ ] E. Teriparatide
Which of the following is the most appropriate treatment?

- 66% A Alendronate
- 6% B Calcitonin
- 10% C Denosumab
- 5% D Raloxifene
- 12% E Teriparatide

Answer & Critique

Correct Answer: A

Educational Objective: Treat postmenopausal osteoporosis.
The most appropriate treatment for this patient is alendronate. The American College of Physicians (ACP) recommends that clinicians offer pharmacologic treatment with alendronate, risedronate, zoledronic acid, or denosumab to reduce the risk for hip and vertebral fractures in women who have known osteoporosis. Individual patient factors and cost help decide which agent is initially used. Bisphosphonates are the most commonly prescribed first-line therapy as they have been shown to reduce the risk of fractures in large, randomized, placebo-controlled trials, and are generally well tolerated with low risk for serious adverse effects.

Although calcitonin increases spine bone mineral density in clinical trials, its anti-fracture efficacy is inconsistent at the spine. The availability of intravenous bisphosphonates and denosumab negates the argument for calcitonin in patients who cannot tolerate oral osteoporosis medications.

Denosumab is effective for prevention of vertebral fracture in postmenopausal women, yet it is expensive and, once started, should be continued indefinitely. Even if followed by intravenous bisphosphonate therapy, discontinuation results in loss of bone mineral density and has been associated with an increased risk of vertebral fracture. Denosumab may be used safely in the setting of compromised kidney function (KDIGO stage G3b and G4). It may also be preferred in patients with poor adherence or tolerance of oral bisphosphonates.

Raloxifene is approved in postmenopausal women for the prevention and treatment of osteoporosis and the prevention of invasive breast cancer in those at high risk. However, raloxifene is contraindicated in those at increased risk of venous thromboembolism. ACP recommends against raloxifene for the treatment of osteoporosis in women.

Teriparatide and abaloparatide are anabolic therapies that reduce the risk of vertebral fracture in postmenopausal osteoporosis. Each increases bone mass and strength of the spine more than antiresorptive drugs and may be preferred if spine bone mineral density is severely low (T-score ≤ −3.5), in patients who fail bisphosphonate therapy, and in glucocorticoid-induced osteoporosis. Neither drug should be prescribed for patients who are at increased risk for osteosarcoma including those with a history of radiation therapy.
Question 37  ★

A 63-year-old woman was diagnosed with osteoporosis 6 years ago. Initial treatment with an oral bisphosphonate resulted in upper gastrointestinal symptoms, so subcutaneous denosumab twice yearly was prescribed. The patient has now completed 5 years of denosumab therapy. Medical history is otherwise unremarkable. Denosumab was last administered 6 months ago.

Vital signs and the remainder of the physical examination are normal.

Which of the following is the most appropriate management?

- A  Continue denosumab
- B  Dual-energy x-ray absorptiometry (DEXA) scan
- C  Osteoporosis drug holiday
- D  Switch to zoledronic acid
Which of the following is the most appropriate management?

- A. Continue denosumab (12%)
- B. Dual-energy x-ray absorptiometry (DEXA) scan (63%)
- C. Osteoporosis drug holiday (19%)
- D. Switch to zoledronic acid (5%)

Answer & Critique

Correct Answer: A

Educational Objective: Manage postmenopausal osteoporosis in patients taking denosumab.

The most appropriate management for this patient is to continue denosumab. Denosumab, a monoclonal antibody against the receptor activator of nuclear factor κB ligand (RANKL), reduces bone resorption by inhibiting the development of osteoclasts. It circulates in the blood for up to 9 months after subcutaneous injection, but once cleared from the circulation, bone resorption transiently but dramatically increases, resulting in an abrupt decline in bone mineral density and, in some cases, vertebral fractures. Once initiated, there is no defined endpoint for cessation of denosumab therapy.

Although bone mineral density increases in response to denosumab therapy, it does not impact management with respect to dose and duration of treatment. Therefore, a DEXA scan is not necessary.

Key Point

When administered subcutaneously twice yearly, denosumab suppresses bone resorption, increases bone density, and reduces the incidence of osteoporotic fractures in men and women; the effects of denosumab are not sustained when treatment is stopped.

Although bone mineral density increases in response to denosumab therapy, it does not impact management with respect to dose and duration of treatment. Therefore, a DEXA scan is not necessary.

In the pharmacologic management of osteoporosis, drug holidays are considered during the course of bisphosphonate therapy. Due to their binding to bone tissue, bisphosphonates have durable effects on bone remodeling and fracture risk after discontinuation. After 5 years of treatment, patients at low risk for fracture can be considered for a bisphosphonate drug holiday. One study showed no cumulative difference in the risk for nonvertebral fractures in women continuing alendronate therapy for 5 versus 10 years. Post hoc analysis of this study showed that women with femoral neck T scores of -2.5 or worse and baseline prevalent vertebral fracture had reduced fracture risk by continuing alendronate therapy for 10 years versus stopping after 5 years compared with placebo.

Zoledronic acid is an intravenous bisphosphonate indicated for the treatment of osteoporosis especially in patients intolerant to oral bisphosphonates. Patients switched from zoledronic acid to denosumab experience further gains in bone mineral density suggesting additive benefit from this sequence of therapy. However, in patients receiving long-term denosumab, switching to zoledronic acid attenuated but did prevent loss of bone mineral density suggesting that denosumab therapy should be continued once initiated.
Question 10 of 84

A 54-year-old woman comes to the office for advice regarding maintaining bone health. She has no history of fracture. The patient recently had a lumpectomy and radiation therapy to treat breast cancer, is currently taking tamoxifen, and will begin taking an aromatase inhibitor in 2 months. She underwent menopause at age 52 years and has persistent hot flushes. Her risk factors for osteoporosis include a slim body habitus and a mother who had a hip fracture at age 67 years.

Physical examination findings, including vital signs, are normal. BMI is 20.

Results of routine laboratory studies are normal.

A dual-energy x-ray absorptiometry scan shows T-scores of −2.1 in the lumbar spine, −2.3 in the femoral neck, and −1.9 in the total hip. Her Fracture Risk Assessment Tool (FRAX) score indicates a 22% risk of major osteoporotic fracture and a 2.4% risk of hip fracture over the next 10 years. Optimal calcium and vitamin D supplementation is recommended, and she is encouraged to begin weight-bearing exercise as tolerated.

Which of the following pharmacologic agents can be started in this patient?

A  Alendronate
B  Denosumab
C  Estrogen
D  Raloxifene
E  Teriparatide
Which of the following pharmacologic agents can be started in this patient?

A. Alendronate
B. Denosumab
C. Estrogen
D. Raloxifene
E. Teriparatide

Answer & Critique  (Correct Answer: A)

**Educational Objective:** Treat a woman with low bone mass.

The most appropriate medication for this patient is alendronate. She has osteopenia, and her major osteoporotic fracture risk by the Fracture Risk Assessment Tool (FRAX) is in a range for which the National Osteoporosis Foundation (NOF) guidelines favor treatment with antiosteoporotic therapy. The NOF recommends antiosteoporotic therapy for persons whose risk of major osteoporotic fracture over the next 10 years is 20% or greater or whose risk of hip fracture over the next 10 years is 3% or greater. Given her current FRAX score and the expectation that she will lose bone mass more rapidly after an aromatase inhibitor is started, it is reasonable to initiate therapy with alendronate now. Alendronate is approved for both osteoporosis prevention and treatment by the FDA.

**Key Point**

- In a patient with osteopenia and a history of radiation therapy, alendronate is the most appropriate drug to use for osteoporosis prevention.
A 66-year-old woman comes to the office for management of osteoporosis discovered on a screening dual-energy x-ray absorptiometry (DEXA) scan. The patient has no personal history of fractures and no family history of parathyroid disease or low bone mineral density. She has hypertension treated with lisinopril but takes no other medications or supplements.

On physical examination, vital signs are normal; BMI is 22. Dentition is good. Other than mild kyphosis, physical examination findings are unremarkable.

**Laboratory studies:**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>4.0 g/dL (40 g/L)</td>
</tr>
<tr>
<td>Calcium</td>
<td>8.7 mg/dL (2.2 mmol/L)</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.7 mg/dL (61.9 µmol/L)</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>2.9 mg/dL (0.94 mmol/L)</td>
</tr>
<tr>
<td>Parathyroid hormone</td>
<td>176 pg/mL (176 ng/L)</td>
</tr>
</tbody>
</table>

The DEXA scan showed T-scores of −2.1 in the lumbar spine, −3.0 in the femoral neck, and −2.5 in the total hip. Radiographs of the lateral spine show no compression fractures.

**Which of the following is the most appropriate next step in management?**

- [ ] A  Measurement of 1,25-dihydroxyvitamin D level
- [ ] B  Measurement of 25-hydroxyvitamin D level
- [ ] C  Parathyroidectomy
- [ ] D  Repeat DEXA scan in 1 year
Which of the following is the most appropriate next step in management?

A. Measurement of 1,25-dihydroxyvitamin D level
B. Measurement of 25-hydroxyvitamin D level
C. Parathyroidectomy
D. Repeat DEXA scan in 1 year

Peer Comparison
This data is from pre-publication test-takers who did not have access to the content of MKSAP 16.

22% 62% 16% 0%

Answer & Critique  (Correct Answer: B)

**Educational Objective:** Diagnose vitamin D deficiency.

This patient's serum 25-hydroxyvitamin D level should be measured. Results of her recent bone mineral density screening showed osteoporosis of the hip, and laboratory studies showed a high parathyroid hormone (PTH) level in the setting of low serum calcium and phosphorus levels. These findings collectively suggest secondary hyperparathyroidism. In this patient with normal kidney function, secondary hyperparathyroidism is likely due to vitamin D deficiency, a common problem in older adults. Therefore, screening her for vitamin D deficiency by measuring the 25-hydroxyvitamin D level would be the most appropriate next step.

A measurement of the 25-hydroxyvitamin D level is more informative in most patients with hypocalcemia than a measurement of the 1,25-dihydroxyvitamin D level because vitamin D deficiency causes hypocalcemia and stimulates PTH secretion, which in turn stimulates conversion of 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D in the kidneys. Therefore, this patient's serum 1,25-dihydroxyvitamin D level may be normal in the setting of vitamin D deficiency and is not useful to check in this setting.

Parathyroidectomy also would be inappropriate in this patient because the elevation in the PTH level is an appropriate physiologic response to the low calcium (and presumed low vitamin D) level.

Repeat dual-energy x-ray absorptiometry testing in 1 year should not be recommended because this patient already has indications for medical management of her osteoporosis after the high PTH and low calcium levels have been evaluated and treated.
When to Refer for Osteoporosis?

- Young people (50-65) with unexpectedly low bone mineral density
- Extremely low bone density (T-score < -3.5)
- Concerns before age 50
- Contemplating teriparatide
- Fractures despite therapy
- Patient contemplating or receiving organ transplant
- Atypical fracture
Remember

Treat women and men age 50 and older if;

- T-score ≤ -2.5 at the femoral neck or spine

- FRAX calculator score:
  - major osteoporosis-related fracture ≥ 20%
  - hip fracture ≥ 3%

- A hip or vertebral (clinical or morphometric) fracture
In Conclusion

- Osteoporosis is a frequent and silent disease
- T-score values help diagnose, Z-score reveal concern for secondary causes of osteoporosis
- Get a BMD in every women 65 or older (USPSTF GL)
- Consider BMD in people >50yo with risk factors and all men >70yo
- Treat!
- Remember to take a break (ha-ha) from anti-resorptive therapy in low risk people after 5-7 years, and then reassess every few years with BMD
Thank You!

Questions?
To Contact Dr. Michael R. Brennan

- Contact the Beaumont Endocrine Center
  23715 Little Mack, Ste 100
  St. Clair Shores, MI 48080
  **Phone:** 586-447-8021
  **Fax:** 586-447-8022

- Call Beaumont Health system and ask to have him paged
  248-898-5000
Bonus case of interest
Real world example over the course of years…
Real world example

OCT-3D PLUS™ Bone Densitometry

Patient: [redacted]
Patient ID: [redacted]
CT Scanner: Philips CT Aura

Age: 49
Sex: F
Exam Date: Apr 10 2013
Exam ID: [redacted]
Referred by: [redacted]

T-Score: -3.0
Z-Score: -1.8

Mean BMD (mg/cc): 91.4

Diagnostic Comments:
The patient has a T-Score below -2.5. According to the WHO criteria, the patient has significantly reduced bone density (Osteoporosis) when compared to young normal persons of the same sex.

Fracture risk approximately doubles exponentially for every 1.0 decrease in T-Score. This patient has a significantly higher risk of osteoporotic fractures when compared to young normal persons of the same sex.

Additional Comments:
How should these results be interpreted?

- Not osteoporosis based on WHO BMD.
- How about the Z-score?
- What was the indication for the study?
- Where are the images?
Repeated Test by PCP

Patient is a 50.2 y/o Female with a diagnosis of osteoporosis, diagnosis code 733.00, per the referral script.

The following summarizes the results of our evaluation:

<table>
<thead>
<tr>
<th>Site</th>
<th>Region</th>
<th>BMD</th>
<th>T-Score</th>
<th>Z-Score</th>
<th>Change from Baseline</th>
<th>Change from Prev.</th>
<th>WHO Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP Spine</td>
<td>L1-L4</td>
<td>0.913 g/cm²</td>
<td>-2.2</td>
<td>-1.3</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>AP Spine</td>
<td>L2-L4</td>
<td>0.921 g/cm²</td>
<td>-2.3</td>
<td>-1.4</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Left</td>
<td>0.712 g/cm²</td>
<td>-2.3</td>
<td>-1.2</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Right</td>
<td>0.727 g/cm²</td>
<td>-2.2</td>
<td>-1.1</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Mean</td>
<td>0.720 g/cm²</td>
<td>-2.3</td>
<td>-1.2</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Total Mean</td>
<td>0.734 g/cm²</td>
<td>-2.2</td>
<td>-1.3</td>
<td>baseline</td>
<td>-</td>
<td>Osteopenia</td>
</tr>
</tbody>
</table>

In order to assist in interpretation of the information in the table above, the following criteria are provided:
- Osteopenia (low bone mass): T-value between -1.0 and -2.5.
- Osteoporosis: T-value of less than -2.5 (e.g. -3.0)

The relative fracture risk increases 2-3 fold for each 10% decrease in bone mineral density below the young adult values. Matched population is for age (T, young adult; Z, age matched) sex, weight, ethnicity.
BMD 1 Year Later

System at William Beaumont Hospital, Troy.

Patient is a 51.3 y/o Female with a diagnosis of osteopenia per the referral script.

The following summarizes the results of our evaluation:

<table>
<thead>
<tr>
<th>Site</th>
<th>Region</th>
<th>BMD</th>
<th>T-Score</th>
<th>Z-Score</th>
<th>Change from Baseline</th>
<th>Change from Prev.</th>
<th>WHO Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP Spine</td>
<td>L1-L4</td>
<td>0.886 g/cm²</td>
<td>-2.4</td>
<td>-1.4</td>
<td>-3.0%</td>
<td>-3.0%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>AP Spine</td>
<td>L2-L4</td>
<td>0.902 g/cm²</td>
<td>-2.5</td>
<td>-1.5</td>
<td>-2.1%</td>
<td>-2.1%</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Left</td>
<td>0.727 g/cm²</td>
<td>-2.2</td>
<td>-1.1</td>
<td>2.1%</td>
<td>2.1%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Right</td>
<td>0.698 g/cm²</td>
<td>-2.4</td>
<td>-1.3</td>
<td>-4.0%</td>
<td>-4.0%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck Mean</td>
<td>0.713 g/cm²</td>
<td>-2.3</td>
<td>-1.2</td>
<td>-1.0%</td>
<td>-1.0%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Total Mean</td>
<td>0.713 g/cm²</td>
<td>-2.3</td>
<td>-1.5</td>
<td>-2.9%</td>
<td>-2.9%</td>
<td>Osteopenia</td>
</tr>
</tbody>
</table>

In order to assist in interpretation of the information in the table above, the following criteria are provided:

Osteopenia (low bone mass): T-value between -1.0 and -2.5.
BMD 1 Year Later

AXIAL SKELETON

Referring Physician: MICHAEL R BRENnan

Birth Date: 08/07/1963 51.3 years
Height / Weight: 62.0 in. 110.0 lbs.
Sex / Ethnic: Female White

Measured: 12/11/2014 1:23:00 PM (13.60)
Analyzed: 12/11/2014 1:26:29 PM (13.60)

Density Ref: AP Spine L1-4 (BMD)

Region BMD (g/cm²) Young-Adult T-score Age-Matched Z-score
L1-L4 0.886 -2.4 -1.4

Density Ref: Left Femur Total (BMD)

Region BMD (g/cm²) Young-Adult T-score Age-Matched Z-score
Total 0.715 -2.3 -1.5

Matched for Age, Weight (females 25-100 kg), Ethnic
USA (Combined NHANES (ages 20-39) / Lunar (ages 20-49)) AP Spine Reference Population (n=112)
Statistically 68% of repeat scans fall within 15D (+ 0.012 g/cm² for AP Spine L1-L4)
Significant Hx, PE, and Studies

- PTH – nml
- Calcium – nml
- Vitamin D – nml (77 in fact)
- TSH – nml
- A1c – nml
- BMI = 20
- Mother fractured hip and pelvis
- Reported menopause 46ish
- Estradiol undetectably low, FSH and LH elevated
FRAX or not to FRAX?
FRAX!

FRAX® WHO Fracture Risk Assessment Tool

Calculation Tool

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

<table>
<thead>
<tr>
<th>Country: US (Caucasian)</th>
<th>Name/ID:</th>
<th>About the risk factors</th>
</tr>
</thead>
</table>

**Questionnaire:**

1. Age (between 40 and 90 years) or Date of Birth
   - Age: 50
   - Date of Birth: M: □, D: □

2. Sex
   - Male □, Female □

3. Weight (kg)
   - 58.97

4. Height (cm)
   - 170.18

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/day
    - No □, Yes □

12. Femoral neck BMD (g/cm²)
    - T-Score: -2.3

**Weight Conversion**

- Pounds ➔ kg
  - 130 ➔ Convert

**Height Conversion**

- Inches ➔ cm
  - 67 ➔ Convert

**BMI: 20.4**

- The ten year probability of fracture (%)
  - with BMD
    - Major osteoporotic: 9.5
    - Hip fracture: 1.7

03461030

Individuals with fracture risk assessed since 1st June 2011
FRAX

- FRAX with risks of positive family history and secondary osteoporosis due to premature menopause (technically not true, but tried to make it seem worse case scenario)

- Worst case
  - 10 yr Major osteoporosis related FRAX risk – 9.5%
  - 10 yr Hip FRAX risk – 1.7%
Treat or not to treat?

- Osteoporosis technically, T-score -2.5 in spine, FRAX says no (mainly because she is so young)
- Why are the bones bad in the mom and the patient, and later we discover the sister has poor BMD as well?..... Hmmm
- Any ideas on what to look for effecting the whole family?
Hypercalciuria

### Component Results

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Ref Range &amp; Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium, Urine</td>
<td>11.7</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Calcium, Urine, Timed</td>
<td>364 (H)</td>
<td>50 - 250 mg/24hr</td>
</tr>
<tr>
<td>Collection Period</td>
<td>24</td>
<td>Hours</td>
</tr>
<tr>
<td>Total Volume</td>
<td>2475</td>
<td>mL</td>
</tr>
</tbody>
</table>

### Result Date - 12/18/2014

#### Component Results

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Ref Range &amp; Units</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium, Urine</td>
<td>18.9</td>
<td>mg/dL</td>
<td>Final</td>
</tr>
<tr>
<td>Comment:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference ranges for random urines or for collections other than 24 hours have not been established.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine, Urine</td>
<td>68.1</td>
<td>mg/dL</td>
<td>Final</td>
</tr>
<tr>
<td>Comment:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference ranges for random urines or for collections other than 24 hours have not been established.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium/Creatinine Ratio, Urine</td>
<td>0.28 (H)</td>
<td>0.02 - 0.26</td>
<td>Final</td>
</tr>
</tbody>
</table>
Hypercalciuria

- Now treatment for the underlying cause, hydrochlorothiazide 25mg daily
  
<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Ref Range &amp; Units</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium, Urine</td>
<td>9.7</td>
<td>mg/dL</td>
<td>Final</td>
</tr>
<tr>
<td>Comment:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference ranges for random urines or for collections other than 24 hours have not been established.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine, Urine</td>
<td>107.1</td>
<td>mg/dL</td>
<td>Final</td>
</tr>
<tr>
<td>Comment:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference ranges for random urines or for collections other than 24 hours have not been established.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium/Creatinine Ratio, Urine</td>
<td>0.09</td>
<td>0.02 – 0.26</td>
<td>Final</td>
</tr>
</tbody>
</table>

- We will see if the treatment works by getting a BMD next December to see if the rate of loss or change in T/Z – scores has slowed
Patient is a 53.3 y/o Female with a diagnosis of osteoporosis per the referral script.

The following summarizes the results of our evaluation:

<table>
<thead>
<tr>
<th>Site</th>
<th>Region</th>
<th>BMD</th>
<th>T-Score</th>
<th>Z-Score</th>
<th>Change from Baseline</th>
<th>Change from Prev.</th>
<th>WHO Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP Spine</td>
<td>L1-L4</td>
<td>0.866 g/cm²</td>
<td>-2.6</td>
<td>-1.4</td>
<td>-5.1%</td>
<td>-2.3%</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>AP Spine</td>
<td>L2-L4</td>
<td>0.869 g/cm²</td>
<td>-2.8</td>
<td>-1.5</td>
<td>-5.6%</td>
<td>-3.7%</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck</td>
<td>0.731 g/cm²</td>
<td>-2.2</td>
<td>-0.9</td>
<td>2.7%</td>
<td>0.6%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>DualFemur</td>
<td>Left</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck</td>
<td>0.689 g/cm²</td>
<td>-2.5</td>
<td>-1.2</td>
<td>-5.2%</td>
<td>-1.3%</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DualFemur</td>
<td>Neck</td>
<td>0.710 g/cm²</td>
<td>-2.4</td>
<td>-1.0</td>
<td>-1.4%</td>
<td>-0.4%</td>
<td>Osteopenia</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DualFemur</td>
<td>Total</td>
<td>0.700 g/cm²</td>
<td>-2.4</td>
<td>-1.4</td>
<td>-4.6%</td>
<td>-1.8%</td>
<td>Osteopenia</td>
</tr>
</tbody>
</table>