



### Key Inforbits

- What is osteoporosis
- Osteoporosis risk factors
- Treatment for osteoporosis
- Screening and diagnosis
- Calcium and vitamin D
- Nonpharmacological approaches

## May is National Osteoporosis Awareness and Prevention Month!

### What is Osteoporosis?



Osteoporosis is a bone disease affecting over 10 million people in the United States with women being four times more likely to develop the disease than men.<sup>1</sup> It is characterized by decrease in bone mass, leaving the bones more fragile and susceptible to breaking. Fractures can occur spontaneously and most often occur from falls of standing distance or less.<sup>1</sup> The most common fractures occurring in osteoporosis patients are those of the hip, spine, and wrist, although any bone can be affected.<sup>1,2</sup> Fractures of the spine can lead to decrease in height and severe back pain. Hip fractures almost always require hospitalization and major surgery and can severely debilitate a person, lessening quality of life or even leading to death.<sup>2</sup> It is important that patients recognize when they are at increased risk of developing osteoporosis so that proper preventative measures can be taken.

1. O'Connell MB, Vondracek SF. Osteoporosis and other metabolic bone diseases. In: Dippiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A pathophysiologic approach. 7<sup>th</sup> ed. New York: McGraw-Hill; 2008. p. 1483-1504.
2. NOF: Standing Tall for You [homepage on the internet] National Osteoporosis Foundation; [cited 2010 April 19] Available from: <http://nof.org/>



### Risk Factors for Osteoporosis<sup>1,2</sup>

- Female gender
- Low body weight
- Alcohol use
- Advanced age
- Low calcium and Vitamin D intake
- Low levels of sex hormones
- Family history of osteoporosis
- Current cigarette use
- Inactive lifestyle
- Use of certain medications (eg, glucocorticoids)
- Certain diseases and conditions (eg, rheumatoid arthritis, anorexia, gastrointestinal diseases)

1. O'Connell MB, Vondracek SF. Osteoporosis and other metabolic bone diseases. In: Dippiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy a pathophysiologic approach. 7<sup>th</sup> ed. New York: McGraw-Hill; 2008. p. 1483-1504.
2. NOF: Standing Tall for You [homepage on the internet] National Osteoporosis Foundation; [cited 2010 April 19] Available from: <http://nof.org/>



### Screening and Diagnosis

Assessing the possibility of osteoporosis should be based on the presence of risk factors.<sup>1</sup>

### Who should be evaluated for risk factors?

- All postmenopausal women or women in menopause transition with specific risk factors
- All men over the age of 50
- Anyone with low trauma fracture history<sup>1</sup>

### Who should be examined for diagnosis?

- Any of the above with risk factors
- Adults who have a fracture after age 50
- Anyone being treated for osteoporosis
- Women age  $\geq 65$  and men age  $\geq 70$  regardless of other factors
- Postmenopausal women who are discontinuing estrogen therapy
- Adults taking medications known to increase risk of osteoporosis (eg, glucocorticoids equivalent to a three month course of 5 mg prednisone or more)<sup>1</sup>
- Adults with certain conditions (eg, RA)<sup>1</sup>

**Diagnosis** of osteoporosis is based on the use of dual-energy x-ray absorptiometry (DXA) to measure hip (femoral neck) and lumbar spine bone mineral density (BMD); sometimes the wrist (radius) may be examined if unable to measure hip or spine. DXA also serves to guide therapy and monitor disease progression. Density is measured in grams per  $\text{cm}^2$  of the area scanned ( $\text{g}/\text{cm}^2$ ). Results are compared to each of two normal values and are expressed in terms of standard deviation (SD) from those norms.

- **Z-score:** the patient's measurement is compared to the usual or expected BMD for other individuals of the same age and sex
- **T-score:** the patient's measurement is compared to the expected value of a young, normal adult of the same sex

T-scores are used for diagnosis or classification of disease

- **Normal:** No more than one SD below the expected value for a young normal adult (T-score = -1)
- **Osteopenia** (low bone mass): between 1 and 2.5 SD below the expected value for a young normal adult (T-score between -1.0 and -2.5)
- **Osteoporosis:** 2.5 SD or more below the expected value for a young normal adult (T-score  $\leq -2.5$ )

A DXA measurement should not serve as the only criteria for diagnosis. Specific secondary causes of bone disease such as hormonal imbalance, malignancy, and other causes should be ruled out with appropriate screening and blood or urine tests.<sup>1</sup>

1. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2010. Available at: [http://www.nof.org/professionals/pdfs/NOF\\_ClinicianGuide2009\\_v7.pdf](http://www.nof.org/professionals/pdfs/NOF_ClinicianGuide2009_v7.pdf)



## Treating Osteoporosis

Although a person may have several risk factors for developing osteoporosis, not everyone should be treated. Those who should be considered for treatment are patients who have a hip or vertebral fracture, a T-score of  $\leq -2.5$  at the femoral neck or spine, or 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  $\geq 3\%$ .<sup>1</sup> There are a number of drugs currently available used to treat or prevent osteoporosis (Table 1). Drug choice depends on patient preference, cost, and patient conditions that may contraindicate drug use.

**Table 1<sup>1,2</sup> Drugs for Osteoporosis**

<b>Drug</b>	<b>Route of Administration</b>	<b>Dosing Schedule</b>	<b>Indication</b>
<b>Bisphosphonates</b>			
Alendronate (Fosamax <sup>®</sup> )	Oral tablet	Daily or weekly	Prevention and treatment
Ibandronate (Boniva <sup>®</sup> )	Oral tablet	Daily, once a month, or every 3 months by IV route	Treatment
	Injection solution		
Risedronate (Actonel <sup>®</sup> )	Oral tablet	Daily, weekly, or once a month	Prevention and treatment
Zoledronic acid (Reclast <sup>®</sup> )	Injection solution	Yearly (treatment) or every 2 years (prevention)	Prevention and treatment
<b>Hormones</b>			
Calcitonin (Miacalcin <sup>®</sup> , Fortical <sup>®</sup> )	Intranasal spray	Daily	Treatment
Teriperatide (Forteo <sup>®</sup> )	Injection solution	Daily	Treatment
<b>Hormone Replacement Therapy</b>			
(Climara <sup>®</sup> , Estrace <sup>®</sup> , Femhrt <sup>®</sup> )	Oral tablet	Daily	Prevention
<b>Selective Estrogen Receptor Modifier</b>			
Raloxifene (Evista <sup>®</sup> )	Oral tablet	Daily	Prevention and treatment

- For patients who take bisphosphonates, it is important to remember to always take them on an empty stomach 30-60 minutes before the first meal of the day with a full glass of water and the patient should remain in an upright position during this time.
- All of the medications listed except ibandronate, calcitonin, HRT, and raloxifene are indicated for use in women and men.


1. NOF: Standing Tall for You [homepage on the internet] National Osteoporosis Foundation; [cited 2010 April 19] Available from: <http://nof.org/>
2. Lexi-Comp Online<sup>™</sup>, Lexi-Drugs Online<sup>™</sup>. Hudson, Ohio: Lexi-Comp, Inc.; 2010; [cited April 19, 2010].



### **Calcium and Vitamin D**

**Calcium** is important in the maintenance of strong bone structure and is only available through diet or supplementation. The average American adult gets approximately 600 mg of elemental calcium daily through dietary sources. If target amounts of calcium cannot be achieved with diet alone, supplementation is recommended for healthy bone development or maintenance as well as for prevention of osteoporosis.<sup>1,2</sup> Only a limited amount of calcium, 350-500 mg, can be absorbed by the gastrointestinal epithelium from any one meal or source; therefore, it is important to divide consumption of calcium-containing products over the course of a day, for example, with meals.<sup>3</sup> Gastric acidity has long been thought to play a role in the efficient absorption of calcium as well. It was once highly regarded that low gastric pH facilitated the absorption of calcium; however, recent studies suggest that this influence isn't as significant as once thought. Nonetheless, it is still recommended that calcium supplements be taken as separate as possible from gastric acid suppressing medications such as histamine-type 2 receptor antagonists (e.g. cimetidine, famotidine) and proton pump inhibitors.<sup>4</sup> Careful consideration should also be made with regard to other drugs such as digoxin, phenytoin, certain antibiotics (eg, fluoroquinolones,

tetracyclines), and bisphosphonates since these drugs may be bound by calcium within the GI tract thus reducing their effects.<sup>4</sup> The most common over the counter (OTC) calcium supplements available come in the form of calcium carbonate and calcium acetate. It is recommended that calcium carbonate be taken with food, as food is known to facilitate calcium absorption; calcium acetate on the other hand can be taken without regard to food.<sup>4</sup>

<u>Recommended daily dietary calcium intake</u>	<u>Foods rich in calcium</u>
<ul style="list-style-type: none"> <li>▪ ≥ 50 yrs old: 1,200-1,500 mg per day</li> <li>▪ 19-49 yrs old: 1,000-1,200 mg per day</li> <li>▪ 9-18 yrs old: 1,300 mg per day</li> <li>▪ 1-8 yrs old: 500- 800 mg per day</li> <li>▪ 6 to 12 months: 270 mg per day</li> <li>▪ Birth to 6 months: 210 mg per day</li> <li>▪ Pregnant or lactating women: 1,000-1300 mg per day<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ Dairy products, eg, milk (not soy), cheese, yogurt</li> <li>▪ Dark leafy vegetables, eg, broccoli, bok choy, and collard greens</li> <li>▪ Tofu</li> <li>▪ Salmon</li> <li>▪ Almonds</li> <li>▪ Food labeled as fortified with calcium<sup>5</sup></li> </ul> 

#### **OTC Calcium Supplements<sup>6</sup>**

<b>Product</b>	<b>Form(s)</b>	<b>Elemental Calcium Content</b>
Calcium Citrate (eg, Caltrate)	Tablet, capsule, gum, suspension, oral powder	Tablet = approx. 200 mg per 500 mg tab
		Capsule = 500 mg per 1,250 mg cap
		Gum = 200 mg per 500 mg gum
		Suspension = 500 mg per 5 mL
		Powder = Not available
Calcium Carbonate (eg, Tums)	Tablet, capsule, suspension	Tablet = 250-500 mg per tab
		Capsule = 180-225 mg per cap
		Suspension = 760 mg per 5 mL
Calcium Glubionate	Liquid	Liquid = Approx. 300 mg per 15 mL
Calcium Gluconate	Tablet, capsule, oral powder	Tablet = 4 5mg per 500 mg tab
		Capsule = 50 mg per 700 mg cap
		Powder = 347 mg per 15 mL
Calcium Lactate (eg, Cal-Lac)	Tablet, capsule	Tablet = 85 mg per tab
		Capsule = 96 mg per tab
Calcium Tri-phosphate (eg, Posture)	Tablet	Tablet = 600 mg per tablet

**Vitamin D** is vital for optimal absorption of both dietary and supplemental calcium from the digestive tract. In response to hormonal controls, vitamin D is activated within the body to act on the

gastrointestinal epithelium to in turn activate calcium binding proteins which facilitate the absorption of calcium immensely. In addition to its role in balancing calcium levels, vitamin D is thought to provide numerous other health benefits within realms of healthcare such as cancer.<sup>1,3</sup>

Vitamin D isn't considered especially abundant in a wide variety of food, but is available in recommended amounts through supplementation. Food sources associated with a higher vitamin D content include cereals, egg yolk, liver, seafood, and those items marked as being fortified with vitamin D. Adequate exposure to sunlight (15 minutes daily to the face and arms will suffice) is important for normal conversion rates of vitamin D to its active form. The recommended daily intake of vitamin D for patients who are considered at risk for osteoporosis is 800-1,000 international units (IU) per day. Up to 2,000 IU daily is currently considered the safe level; however, new and ongoing research may indicate more.<sup>1,2,5</sup>



1. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2010. Available at: [http://www.nof.org/professionals/pdfs/NOF\\_ClinicianGuide2009\\_v7.pdf](http://www.nof.org/professionals/pdfs/NOF_ClinicianGuide2009_v7.pdf)
2. Calcium and Bone Health [cdc.gov] Atlanta, GA: Centers for Disease Control and Prevention; [updated 2008 December 3; cited 2010 April 20] Nutrition for Everyone [1 screen] Available at: <http://www.cdc.gov/nutrition/everyone/basics/vitamins/calcium.html>
3. Guyton AC, Hall JE. Parathyroid Hormone, Calcitonin, Calcium and Phosphate Metabolism, Vitamin D, Bone, and Teeth. In: Textbook of Medical Physiology. 11<sup>th</sup> ed. Philadelphia, PA: Elsevier Inc; 2006. p. 978-995
4. Sunyecz JA, The use of calcium and vitamin D in the management of osteoporosis. Therapeutics and Clinical Risk Management 2008;4(4):827-836
5. O'Connell MB, Vondracek SF. Osteoporosis and other metabolic bone diseases. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A pathophysiologic approach. 7<sup>th</sup> ed. New York: McGraw-Hill; 2008. p. 1483-1504.
6. Calcium, Calcium citrate, Calcium carbonate, Calcium glubionate, Calcium gluconate, Calcium lactate, Calcium tri-phosphate. In: Drug Facts and Comparisons (Facts and Comparisons eAnswers) [AUHSOP Intranet]. St. Louis: Wolters Kluwer Health [updated Dec 2009, cited 2010 Apr 23]. [about 8 p.]. Available from <http://online.factsandcomparisons.com>

### **Nonpharmacologic Prevention and Management**

In addition to OTC supplements, preventative measures can help to decrease risk of osteoporosis and can to decrease the likelihood of a new or recurrent fracture if you have been diagnosed with osteoporosis.<sup>1</sup> A healthy lifestyle are effective at helping to prevent osteoporosis, including a balanced diet, fall prevention, and physical activity.<sup>1,2</sup> The following chart lists these tips for reducing the risk of a fracture.

<b>Diet<sup>1</sup></b>	<b>Physical Activity</b>	<b>Fall Prevention at Home</b>	<b>Other Tips</b>
<ul style="list-style-type: none"> <li>▪ Limit intake of soda and other carbonated beverages</li> <li>▪ Limit caffeine to 2-4 servings/day</li> <li>▪ Restrict sodium intake (&lt;2.4 g/day)</li> <li>▪ Consider taking a multivitamin to ensure adequate intake of vitamins and minerals</li> <li>▪ Consume adequate dietary protein (especially animal protein)</li> <li>▪ Consume dietary soy</li> </ul>	<ul style="list-style-type: none"> <li>▪ Maintain good posture<sup>2</sup></li> <li>▪ Have a regular exercise routine to improve agility, strength, and balance<sup>1</sup> <ul style="list-style-type: none"> <li>oeg, Tai Chi, yoga</li> </ul> </li> <li>▪ Engage in moderate-intensity weight bearing exercises at least 30 min daily most days of the week<sup>1</sup> <ul style="list-style-type: none"> <li>oeg, walk, jog, climb stairs</li> </ul> </li> <li>▪ Perform resistance exercises 20-30 min at least twice weekly<sup>1</sup> <ul style="list-style-type: none"> <li>oeg, free weights, elastic bands, weight machine</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Keep rooms clutter-free</li> <li>▪ Wear low-heeled shoes<sup>2</sup></li> <li>▪ Maintain well-lit rooms<sup>1,2</sup></li> <li>▪ Keep a flashlight by the bedside<sup>1</sup></li> <li>▪ Use rugs with nonslip back<sup>1</sup></li> <li>▪ Use handrails when taking the stairs<sup>1</sup></li> <li>▪ Install grab bars in shower/tub area<sup>1,2</sup></li> <li>▪ Place nonskid strips, mats, or decals in tub/shower<sup>1</sup></li> <li>▪ Install a seat in shower or bathtub<sup>1</sup></li> <li>▪ Install elevated toilet seats<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ Quit smoking<sup>1</sup></li> <li>▪ Practice moderation with alcoholic beverages (women: ≤1 drink/day; men: ≤2 drinks/day)<sup>1</sup></li> <li>▪ Have a periodic medication review for agents that can increase risk of falls<sup>1</sup></li> <li>▪ Rise slowly from a seated position<sup>1</sup></li> <li>▪ Have an annual eye exam<sup>1</sup></li> <li>▪ Discuss pain management options with your doctor<sup>2</sup></li> <li>▪ May use hip protectors to help cushion sideways falls<sup>1</sup></li> </ul>

1. O'Connell MB, Vondracek SF. Osteoporosis and other metabolic bone diseases. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A pathophysiologic approach. 7<sup>th</sup> edition. McGraw Hill Medical. New York: 2008, pp. 1483-1504.
2. Mayo Clinic Staff. Osteoporosis. December 12, 2009 [accessed on April 16, 2010]. Available from <http://www.mayoclinic.com/health/osteoporosis/DS00128>.



### **From the Medical Literature**

Bisphosphonates have been in the news recently due to their potential to cause osteonecrosis of the jaw (ONJ). This complication occurs in cancer patients who are not receiving radiation therapy to the head or neck.<sup>2</sup> ONJ involves bone exposure in the oral cavity with corresponding inflammation around the affected region.<sup>2</sup> The frequency of occurrence is estimated to be as high as 10% in this patient population.<sup>2</sup> The more potent bisphosphonates are associated with the greatest risk of ONJ.<sup>2</sup> Early identification, prompt management, and minimization risk through routine dental care are recommended for patients at risk for this condition.<sup>2</sup>

Emerging news has also suggested a potential increased risk for fractures below the hip joint. These safety concerns come after published case reports indicated that subtrochanteric femur fractures occurred in women taking oral bisphosphonates.<sup>1</sup> Data from two large observational studies in patients with osteoporosis published in the Journal of Bone and Mineral Research failed to show the increased risk with oral bisphosphonates.<sup>1</sup> The FDA's investigation into available data regarding oral bisphosphonates and these fractures remains inconclusive.<sup>1</sup> The FDA and other outside experts continue to examine the alleged link and the FDA will continue to update the public as new information is discovered.<sup>1</sup>

1. FDA drug safety communication: ongoing safety review of oral bisphosphonates and atypical subtrochanteric femur fractures. March 10, 2010 [accessed on April 16, 2010]. Available from <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm203891.htm>.
2. Gebara SN, Moubayed GH. Risk of osteonecrosis of the jaw in cancer patients taking bisphosphonates. Am J Health-Syst Pharm 2009;66:1541-1547.



### **For More Information About Osteoporosis**

- National Osteoporosis Foundation: (800)-231-4222 or [www.nof.org](http://www.nof.org)
- Inspire (Osteoporosis Support Group): [www.inspire.com](http://www.inspire.com)
- Know My Bones: [www.knowmybones.com](http://www.knowmybones.com)



### **The last "dose" ...**

*"When you get to the end of your rope, tie a knot and hang on."  
Franklin D. Roosevelt [1882 - 1945]*

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