Osteoporosis: An Overview

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ABSTRACT

Osteoporosis is a condition of reduced bone mass that results in fractures and significant pain that can occur anywhere in the body. It generally results in elderly individuals but can occur in any age group due to nutritional deficits and hormonal changes. Nurses play an important role in educating patients and promoting prevention of bone injury, such as lifestyle changes and fall prevention. This study focuses on disease etiology, progression and prevention of injury, including medical regimens to reduce osteopenia and bone loss.
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Policy Statement

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This educational activity is credited for 2 hours. Nurses may only claim credit commensurate with the credit awarded for completion of this course activity.

Pharmacology content is 1 hour (60 minutes).

Statement of Learning Need

Nurses caring for individuals with osteoporosis as well as their families need continuing learning to understand the disorder, health risks and prevention strategies involved.

Course Purpose

To provide an overview of osteoporosis, including its prevalence, signs and symptoms, diagnosis, prevention, and treatment.
**Target Audience**

Advanced Practice Registered Nurses and Registered Nurses

(Interdisciplinary Health Team Members, including Vocational Nurses and Medical Assistants may obtain a *Certificate of Completion*).

**Course Author & Planning Team Conflict of Interest Disclosures**

Dana Bartlett, RN, BSN, MA, MSN, William S. Cook, PhD,
Douglas Lawrence, MA, Susan DePasquale, MSN, FPMHNP-BC - all have no disclosures.

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Please take time to complete a self-assessment of knowledge, on page 4, sample questions *before* reading the article.

Opportunity to complete a self-assessment of knowledge learned will be provided at the end of the course.
1. Approximately 80% of the cases of osteoporosis in the United States occur in
   a. women
   b. African Americans
   c. men
   d. young adults

2. Osteoporosis is caused by a disruption in
   a. calcium absorption
   b. blood supply to the bones
   c. bone remodeling
   d. the nerve fibers of the bones

3. Post-menopausal osteoporosis is primarily caused by
   a. an increase in serum parathyroid hormone levels
   b. decreased production of estrogen
   c. decreased intake and absorption of vitamin D
   d. decreased blood supply to the bones

4. Age-related osteoporosis is primarily caused by
   a. decreased exposure to sunlight
   b. decreased production of estrogen and testosterone
   c. increased renal excretion of calcium and vitamin D
   d. a decrease in the number of functioning osteoblasts

5. Which of these is considered first-line treatment for osteoporosis?
   a. Calcitonin
   b. Parathyroid hormone
   c. Vitamin D and calcium supplementation
   d. Biphosphonates
Introduction

Osteoporosis is a chronic bone disease that affects millions of Americans. It is characterized by an imbalance between bone growth and bone breakdown that results in decreased bone mass and an increased risk of fractures. The disease is progressive and clinically silent, and in many cases it is not detected until someone who has osteoporosis breaks a bone or has a diagnostic screening test. Treatment can stop the progression of the disease but cannot reverse osteoarthritis that is established.

Epidemiology

Approximately 54 million Americans have osteoporosis and/or low bone mass, and osteoporosis is the most common metabolic bone disorder in the United States. Approximately 80% of all cases of osteoporosis in the United States occur in women, but it has been estimated that about 1.5 million American men over age 65 have osteoporosis. The incidence of osteoporosis is lower in African Americans. The incidence of osteoporosis increases with age and the majority of women between the ages of 70-80 meet the clinical criteria for osteoporosis.

Definition of osteoporosis and pathophysiology

The World Health Organization (WHO) defines osteoporosis as “... a systemic skeletal disease characterized by low bone density and microarchitectural deterioration of bone tissue with a consequent increase in bone fragility.”
The basic cause of osteoporosis is a disruption of bone remodeling. Bone remodeling is comprised of two processes, bone resorption and bone formation. Bone resorption is the breakdown of mature bone by cells called osteoclasts. Bone formation is the construction of new bone by cells called osteoblasts. When bone construction cannot match bone resorption there is a net bone loss and osteoporosis results.

Causes Of Osteoporosis

Osteoporosis is classified as primary or secondary. Primary osteoporosis is a bone disease that is related to aging and hormonal shifts, in the absence of any disease or condition known to cause osteoporosis. There are two types of primary osteoporosis that affect adults, post-menopausal osteoporosis and age-associated osteoporosis. Post-menopausal osteoporosis is caused by decrease production of estrogen, which in turn increases the activity of osteoclasts. Age-associated osteoporosis is caused by a progressive decrease in the number of functioning osteoblasts.

Secondary osteoporosis is caused by a disease process, a medication, or a lifestyle factor. A list of drugs and diseases that may cause secondary osteoporosis is in Table 1. In addition, any condition that leads to a lack of mobility such as a stroke or advanced Parkinson’s disease may result in reduced bone mass and would be considered a risk factor for developing osteoporosis.
# TABLE 1: Conditions, Diseases and Medications That Cause or Contribute to Osteoporosis and Fractures

## LIFESTYLE FACTORS:
- Alcohol abuse
- Frequent falling
- Inadequate physical activity
- Excessive thinness
- High salt intake
- Low calcium intake
- Excess Vitamin A
- Immobilization
- Smoking (active or passive)

## GENETIC DISEASES:
- Cystic fibrosis
- Ehlers-Danlos syndrome
- Gaucher’s disease
- Glycogen storage diseases
- Hemochromatosis
- Homocystinuria
- Hypophosphatasa
- Marfan syndrome
- Menkes steely hair syndrome
- Osteogenesis imperfecta
- Parental history of hip fracture
- Riley-Day syndrome

## HYPOGONADAL STATES:
- Androgen insensitivity
- Anorexia nervosa
- Athletic amenorrhea
- Hyperprolactinemia
- Panhypopituitarism
- Premature menopause (<40 yrs)
- Turner’s & Klinefelter’s syndromes
- Endocrine disorders
- Central obesity
- Cushing’s syndrome
- Diabetes mellitus (Types 1 & 2)
- Hyperparathyroidism
- Thyrotoxicosis
GASTROINTESTINAL DISORDERS:

Celiac disease  Gastric bypass  Gastrointestinal surgery
Inflammatory bowel disease  Malabsorption  Pancreatic disease
Primary biliary cirrhosis

HEMATOLOGIC DISORDERS:

Hemophilia  Leukemia and lymphomas  Monoclonal gammopathies
Multiple myeloma  Sickle cell disease  Systemic mastocytosis
Thalassemia

RHEUMATOLOGIC AND AUTOIMMUNE DISEASES:

Ankylosing spondylitis  Other rheumatic and autoimmune diseases
Rheumatoid arthritis  Systemic lupus

NEUROLOGICAL AND MUSCULOSKELETAL RISK FACTORS:

Epilepsy  Multiple sclerosis  Muscular dystrophy
Parkinson’s disease  Spinal cord injury  Stroke

MISCELLANEOUS CONDITIONS AND DISEASES:

AIDS/HIV  Alcoholism  Amyloidosis
Chronic metabolic acidosis  Chronic obstructive lung disease  Congestive heart failure
Depression  End stage renal disease  Hypercalciuria
Idiopathic scoliosis  Post-transplant bone disease  Sarcoidosis
Weight loss
### MEDICATIONS:

<table>
<thead>
<tr>
<th>Aluminum (in antacids)</th>
<th>Anticoagulants</th>
<th>Anticonvulsants</th>
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<tr>
<td></td>
<td>(heparin)</td>
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<tr>
<td>Aromatase inhibitors</td>
<td>Barbiturates</td>
<td>Cancer</td>
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<td>chemotherapeutic</td>
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<td>drugs</td>
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<td>Depo-medroxyprogesterone</td>
<td>Glucocorticoids (≥ 5 mg/d prednisone or equivalent for ≥ 3 months)</td>
<td>GnRH (Gonadotropin releasing hormone)</td>
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<td>(premenopausal contraception)</td>
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<td>agonists</td>
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<td>Lithium Cyclosporine A and tacrolimus</td>
<td>Methotrexate</td>
<td>Parenteral nutrition</td>
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<tr>
<td>Proton pump inhibitors</td>
<td>Selective serotonin reuptake inhibitors (SSRIs)</td>
<td></td>
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<tr>
<td>Tamoxifen® (premenopausal use)</td>
<td>Thiazolidinediones (Actos® and Avandia®)</td>
<td>Thyroid hormones (in excess)</td>
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</table>

### Risk Factors for Osteoporosis

Factors that increase the likelihood of developing osteoporosis include:

- Alcohol use > three drinks a day
- Advanced age
- Anticonvulsants
- Ethnicity: Asian and Caucasian
- Family history of osteoporosis
- Female gender
- Hypogonadism
- Low body mass index
- Low calcium intake
• Premature menopause
• Previous fractures
• Sedentary life style
• Thyroid excess
• Smoking

Some of the risk factors can be remembered by using the mnemonic *ostoporosis*.

• Low calcium intake
• Seizure medications (anticonvulsants)
• Thin build
• Ethanol intake
• Hypogonadism
• Previous fracture
• Thyroid excess
• Race (Caucasian, Asian)
• Other relatives with osteoporosis
• Steroids
• Inactivity
• Smoking

The World Health Organization (WHO) has developed an algorithm that uses risk factors to calculate the 10-year risk of a hip fracture or any other major fracture caused by osteoporosis. This assessment tool is called

The FRAX tool can be viewed online at [http://www.shef.ac.uk/FRAX/](http://www.shef.ac.uk/FRAX/).

Click on *Calculation Tool* and follow the instructions.
the fracture-risk algorithm, *FRAX*, and it uses these criteria.

- Alcohol intake
- Gender
- Family history of hip fracture
- History of fracture
- Low body mass index
- Use of oral glucocorticoid therapy
- Secondary osteoporosis (*i.e.*, coexistence of rheumatoid arthritis)
- Tobacco use Current smoking status

The National Osteoporosis Foundation (NOF) guidelines notes the following restrictions for the FRAX tool:

1) it is intended to be used for post-menopausal women and men 50 years of age and older; 2) it was not intended to be used for young adults or children; 3) the validity of the FRAX tool has been evaluated in patients who are currently receiving drug therapy for osteoporosis or who previously received drug therapy for osteoporosis; and, 4) the femoral neck bone mineral density is preferred when using the FRAX tool.  

**Risk Factors for Falls**

Most fractures in patients who have osteoporosis are caused by falls. Some of the risk factors that increase the chances of falling are listed in Table 2. The NOF Clinician's Guidelines can be accessed for more information; it contains the latest information on how to screen individuals with osteoporosis for their risk of fall injury or bone fractures and on the best methods to evaluate them, including biochemical markers in men and
women relative to bone health and the use of supplementation such as calcium and vitamin D.

### Table 2: Risk factors that increase the chances of falling

- Poor lighting
- Slippery floor surfaces
- Advanced age
- Dehydration
- Medications that cause sedation
- Orthostatic hypotension
- Poor balance
- Poor vision
- Previous falls
- Urinary incontinence or urgency

### Signs and Symptoms

Osteoporosis is typically not associated with any specific signs or symptoms. Some patients may complain of back pain that is caused by a vertebral collapse or fracture. Another common presenting symptom is loss of height with progressive kyphosis. Fractures in other parts of the body may also occur with minimal or no trauma in someone with osteoporosis.

### Complications

The most common complication of osteoporosis is fracture. It has been estimated that each year in the United States osteoporosis is the cause of almost 1.5 million fractures, and fractures of the vertebrae, proximal femur...
(hip), and distal forearm are the most common. The lifetime incidence of fractures caused by osteoporosis is 40%-50% for women and 13%-22% for men, and approximately 90% of hip and spine fractures in elderly women are caused by osteoporosis.

Hip fractures are especially serious. Only 40% of those who suffer a hip fracture regain their previous level of independence, and hip fractures can cause chronic pain, increased mortality, and loss of function and mobility. Vertebral fractures and fractures of the forearm are also a significant cause of disability, pain, and limitations to activity. Fractures caused by osteoporosis are not always preceded by noticeable trauma.

**Diagnosis Of Osteoporosis**

The diagnosis of osteoporosis is often made on screening. The use of dual-energy X-ray absorptiometry (DEXA) measures bone mineral density and is the preferred method for measuring bone mineral density and diagnosing osteoporosis. The National Osteoporosis Foundation recommends bone mineral density testing in:
- all women age 65 and older
- all men age 70 and older
- postmenopausal women and men above age 50-69, based on risk factor profile

A DEXA scan compares the bone density of the person being tested to that of a person 20 - 29 years of age. A score (called a T-score) is reported, with an average bone density score of zero. Scores above zero indicate more dense bones than the average person 20 – 29 years of age; and, scores less
than zero indicate less dense bones than the average person 20 – 29 years of age. Osteopenia (bones that are thinner than average but not thin enough to be classified as osteoporosis) is diagnosed when the T-score falls between −1.0 and −2.4. Individuals that have T-scores less than or equal to −2.5 have osteoporosis.\(^2\)

When the diagnosis of osteoporosis is made, other laboratory tests may be done in selected cases to help rule out secondary causes and to help guide the treatment of osteoporosis. Tests that may be done include:\(^7\)

- Complete blood count
- Calcium level
- Liver function tests
- Magnesium level
- Parathyroid hormone (PTH) level
- Phosphorus level
- Renal function tests
- Testosterone and gonadotropin levels in younger men
- Vitamin D level

The use of the DEXA scan is the gold standard, but sometimes other tests are done. Computed tomography scanning can also be used to evaluate the bone density, but it is more expensive and requires higher doses of radiation than the DEXA scan, and is therefore infrequently used.\(^5\) Plain x-ray can rule out fractures, but they are not sensitive enough to detect osteoporosis until a patient’s bone density has decreased by 50%.\(^7\)
Lifestyle factors that may affect bone health include diet, exercise, cigarette smoking cessation, and the use of alcohol. Lifestyle factors influencing the development of osteoporosis are discussed in this section.

**Diet**

Insufficient dietary calcium levels have been identified as a risk factor for the development of osteoporosis, and calcium supplementation is often recommended for people at risk for osteoporosis. The National Osteoporosis Foundation supports the recommendations of the Institute of Medicine for calcium intake:7

- women age 51 and older and men age 50 - 70 should consume 1000 mg of calcium a day
- women 51 and older and men older than 71 should consume 1200 mg of calcium a day

The 2014 Clinician’s Guidelines from the NOF notes that clinical trials have shown that dietary supplementation with calcium and vitamin D can reduce the risk of fractures, but the preventive role of calcium supplementation is not clear. Vitamin D deficiency is an important consideration in bone health that is further discussed below. Meta-analyses of the literature do not show that calcium supplementation has a significant effect for preventing fractures, and the use of calcium supplements can have harmful cardiovascular, renal, and gastrointestinal effects,10 so the decision to use or not use calcium supplementation must be made on a case by case basis.

Vitamin D deficiency has also been identified as a risk factor for developing osteoporosis which is widespread,11 and the NOF recommends 800-1000 IU
of vitamin D every day for people age 50 and older. Vitamin D is needed for calcium absorption, and it helps increase muscle strength. Some of the pharmacologic treatments for osteoporosis require adequate levels of vitamin D.\(^{12}\) However, there is no unequivocal evidence that increasing vitamin D levels helps to reduce the risk of fractures or prevents bone loss,\(^{13-15}\) so as with calcium, the decision to use or not use vitamin D supplementation must be made on a case by case basis.

**Physical Exercise**

Physical exercise can help increase bone mass and it strengthens muscle, reducing the risk of fractures and the risk of falls,\(^{16}\) and the NOF recommends exercise as a preventive measure for people at risk for osteoporosis.

How much exercise and what type of exercise is needed to increase bone mass is not clear.\(^{16}\) Additionally, it is uncertain that increasing bone mass is the endpoint that should be used to measure the preventive effectiveness of exercise.\(^{17}\) It may be that fall prevention through muscle strengthening is why physical exercise is important for people who have or are at risk of developing osteoporosis.\(^{17}\) Non-weight bearing physical exercise, while good for the cardiovascular system, is not optimal to build and maintain bone health, but it does encourage physical activity so it can be helpful for fall prevention. Weight bearing exercises are preferred for patients who have, or at risk for developing osteoporosis.

**Smoking**
Smoking has long been recognized as a risk factor for developing osteoporosis. Women who smoke have lower bone mineral density than women who do not, reach menopause several years earlier than non-smoking women,\(^{18}\) and increase their risk of fractures.\(^{19}\) In women who smoke, these effects may be caused in part by decreased calcium and estradiol levels and lower body mass index.\(^{19}\) However, the association between smoking and fractures in women appears to persist even when body mass is accounted for and smoking has been reported to be a risk factor for a low bone mineral density and fractures in men, as well.\(^{20}\) The mechanisms by which smoking decreases bone mineral density are not completely understood, but the NOF recommends smoking cessation as an osteoporosis intervention.

**Alcohol Consumption**

Alcohol has also been identified as a risk factor for the development of osteoporosis. The effects of alcohol on the development of osteoporosis are complex and include a direct, negative effect on the osteoblasts, and endocrine and nutritional deficiencies that are secondary to alcoholism.\(^{21}\) Alcohol is considered to be an independent risk factor for the development of osteoporosis,\(^{22}\) and there is an inverse relationship between the amount of alcohol consumed and the duration of drinking and osteoporosis.\(^{21}\) The NOF notes in the 2014 guidelines that more than two drinks a day for women and more than three drinks a day for men may be detrimental to bone health.\(^{8}\)
Caffeine

High intake of coffee, usually estimated to be ≥ four cups a day, has been identified as a possible risk factor for the development of osteoporosis. Caffeine may be directly harmful to osteoblasts or it may increase urinary excretion of caffeine and decrease the intestinal absorption of caffeine. The mechanism or mechanisms by which caffeine may affect bone mineral density are not clearly understood, and several recent (2013) studies did not find an association between high caffeine intake and a significant decrease in bone mineral density or an increased risk of fractures.

Treatment Of Osteoporosis

The goals of treatment of osteoporosis are: 1) to attenuate or prevent bone loss; and, 2) prevent falls and fractures. All persons at risk for osteoporosis should be evaluated for fall risk and be encouraged to make dietary and lifestyle changes that can help increase bone mineral density and prevent fractures.

The NOF recommends considering pharmacological treatment in postmenopausal women and men over the age of 50 if the patient has a:

- clinically or radiologically confirmed hip or vertebral fracture
- T-score ≤ -2.5 at the femoral neck, total hip or lumbar spine
- low bone mass (T-score between -1.0 and -2.5 at the femoral neck or lumbar spine) and a 10-year probability of a hip fracture ≥3 percent or a 10-year probability of a major osteoporosis-related fracture ≥20 percent based on the US FRAX algorithm
Pharmacological Therapy for Osteoporosis

The medications that are currently (2014) approved by the Food and Drug Administration (FDA) for the treatment of osteoporosis are: 1) bisphosphonate derivatives; 2) calcitonin; 3) estrogen agonist/antagonist; 4) estrogens or hormone therapy; 5) parathyroid hormone; and, 6) RANKL inhibitor.

Bisphosphonate derivatives

Bisphosphonate derivatives are considered to be the first-line therapy for the treatment of osteoporosis. These drugs are referred to in the pharmacological literature as bisphosphonate derivatives, but are commonly called bisphophonates. The bisphosphonates that are currently FDA approved for the prevention or treatment of osteoporosis are: alendronate (Fosamax®), ibandronate (Boniva®) risedronate (Actonel®), and zolendronic acid (Reclast®). The basic mechanism of action of these drugs is inhibition of bone resorption by inhibiting the action of osteoclasts and osteoclast precursors.

The bisphosphonates have been proven to prevent fractures in patients who have osteoporosis, and there is also evidence that these drugs decrease morbidity and mortality. Alendronate has been reported to reduce the incidence of spine and hip fractures by 50% in patients who have had a spine fracture or who have osteoporosis of the hip, and similar results have been reported for the other bisphosphonates. These drugs are available as oral or IV medications and, depending on the patient’s need and the formulation, they are prescribed once a day, once a week, monthly, or every
three months. In the case of Reclast®, an IV infusion is given every two years.

The oral bisphosphonates must be taken correctly to ensure that they are effective and to avoid side effects. Patients that are prescribed an oral bisphosphonate should be given the following instructions.

- Take the bisphosphonate at least 30-60 minutes before the first food, drink, or drugs of the day: the amount of time recommended varies for each drug.
- Do not lie down for at least 30-60 minutes after taking the drug: the amount of time varies for each specific bisphosphonate.
- Take with a full glass of water - no other liquids, only water.
- If a dose is missed, wait until the following morning to take a dose.

Food and any liquid aside from water can interfere with absorption of the medication. The bisphosphonate derivatives can cause erosion to the esophagus, and maintaining an upright posture for 30-60 minutes after ingestion is recommended to avoid injury to the esophageal mucosa. This time limit also allows for complete drug absorption and maximal improvement in bone mineral density.29

The most common side effects of the bisphosphonates are gastrointestinal: constipation, diarrhea, heartburn, and esophageal irritation. Hypocalcemia is uncommon, but patients taking these drugs should be monitored to be sure they are receiving the recommended dietary intake of calcium and vitamin D. In high doses the bisphosphonates are toxic to the kidney.27 Also, approximately 50% of bisphosphonates are excreted unchanged and renal
Impairment can cause an accumulation of the drug. Because of their potential for nephrotoxicity and the decreased excretion of these drugs in patients who have renal impairment, the bisphosphonates typically are contraindicated if the patient has a glomerular filtration rate < 30–35 mL/minute. However, this is considered to be a guideline not an absolute contraindication.

The level of renal impairment at which drug accumulation becomes clinically relevant is not known, and there is some clinical experience with the use of bisphosphonates in patients who have an advanced stage of kidney disease.

The four most serious complications that have been associated with bisphosphonate therapy are: 1) osteonecrosis of the jaw; 2) atypical fracture of the femur; 3) atrial fibrillation; and, 4) esophageal cancer. These complications are discussed in more detail below.

Osteonecrosis of the jaw:

Osteonecrosis of the jaw is defined as “... the presence of exposed bone in the maxillofacial region that does not heal within 8 weeks of identification by a healthcare provider.” This complication is seen most often in patients who have cancer and are being treated with high doses of IV bisphosphonates. Osteonecrosis of the jaw, as an adverse effect of bisphosphonate therapy, is quite rare when these drugs are prescribed for post-menopausal women who do not have pre-disposing risk factors. A 2011 study noted an incidence of 0.001% of this complication in patients...
who were taking a bisphosphonate and did not have cancer\textsuperscript{31} and other sources have estimated the risk to be quite low, as well.\textsuperscript{27}

Invasive dental procedures and poor dental hygiene have also been identified as risk factors for developing osteonecrosis of the jaw while taking bisphosphonates. The prescribing provider should identify this risk to the patient and their dentist prior to an invasive dental procedure, and advise the patient to maintain good dental hygiene while taking a bisphosphonate.\textsuperscript{29}

Atypical fracture of the femur:\textsuperscript{28}

An atypical fracture of the femur is defined by -

- location in the subtrochanteric region or femur shaft
- minimal or no trauma
- transverse or short oblique fracture line
- absence of commination
- a medial spike with complete fracture

There are some indications that patients who are taking bisphosphonates for a long period of time may have an increased risk for this type of fractures.\textsuperscript{28,29} However, many of the research findings are limited because they were derived from case studies or observational series or the study designs had methodological errors, and there is no evidence that unequivocally supports a cause and effect relationship between the use of these drugs and atypical fractures of the femur.\textsuperscript{28} Yet, even if the bisphosphonates were a direct cause of this complication, the risk of developing an atypical fracture of the femur is considered to be very low and
is far outweighed by the number of hip fractures that are prevented by the use of bisphosphonates.\textsuperscript{28,29}

Atrial fibrillation:

A 2007 study was the first to propose a link between the use of bisphosphonates and an increased incidence of atrial fibrillation.\textsuperscript{32} Obviously, many patients who are prescribed a bisphosphonate have pre-existing risk factors for developing atrial fibrillation, \textit{i.e.}, atherosclerosis and advanced age, and subsequent research has neither confirmed nor disproved the association between atrial fibrillation and the use of bisphosphonates.\textsuperscript{29} However, in a recent (2014) review of the literature the authors noted that the risk of new-onset atrial fibrillation was slightly increased by the use of both intravenous and oral bisphosphonates, with the risk in intravenous use being higher than that of oral use.\textsuperscript{33} The authors pointed out that the pathogenic mechanisms by which the bisphosphonates might cause atrial fibrillation are unknown and that their study did \textit{not} definitely establish a cause and effect relationship.

Esophageal cancer:

Between the introduction of alendronate in 1995 and 2008 the FDA received 23 reports of esophageal cancer in which alendronate was suspected to be the causal factor.\textsuperscript{34} Subsequent to that, two large observational studies provided further evidence of a positive association between the use of bisphosphonates and an increased risk of esophageal cancer.\textsuperscript{35,36} Esophagitis and esophageal ulceration are adverse effects of the bisphosphonates and they are risk factors for developing esophageal cancer. However, at this time a definite link between bisphosphonates and
esophageal cancer has not been established, and the FDA has not concluded that people taking the oral bisphosphonates have an increased risk for developing esophageal cancer.

*Calcitonin*

Calcitonin is a hormone that is secreted by the thyroid gland. Calcitonin inhibits the activity of osteoclasts and decreases bone resorption. Calcitonin has a labeled use for the treatment of post-menopausal osteoporosis, and synthetic calcitonin is available as a nasal spray (Fortical®, Miacalin®) or an injectable (Miacalcin®) that can be given intramuscularly or subcutaneously.

Calcitonin has been shown to increase bone mineral density. However, there is limited evidence for its efficacy in decreasing the incidence of fractures, and the FDA, the manufacturer of Miacalcin® nasal spray, and other sources concluded that there is an increased risk of malignancies in patients treated with calcitonin (4.1%) versus patients treated with placebo (2.9%). The FDA noted the following:

“In a meta-analysis of 21 randomized, controlled clinical trials with calcitonin-salmon (nasal spray or investigational oral formulations), the overall incidence of malignancies reported was higher among calcitonin-salmon-treated patients (4.1%) compared with placebo-treated patients (2.9%). This suggests an increased risk of malignancies in calcitonin-salmon-treated patients compared to placebo-treated patients. The benefits for the individual patient should be carefully considered against possible risks.”

*Estrogen agonist/antagonists*
The estrogen agonist/antagonists, which are occasionally called selective estrogen receptor modulators, are medications, which combine estrogen receptor agonist activity in bone and estrogen receptor antagonist activity in breast and uterine tissue. These drugs bind to estrogen receptors in the bone and increase the activity of estrogen. This in turn directly and indirectly inhibits the activity of osteoclasts and decreases bone resorption.\textsuperscript{43-45}

There are two estrogen agonist/antagonists that are currently FDA approved for the treatment and prevention of post-menopausal osteoporosis: raloxifene (Evista\textsuperscript{®}) and bazedoxifene (Duavee\textsuperscript{®}), which is a combination of a conjugated estrogen and a selective estrogen receptor modulator. These drugs have both been shown to significantly reduce the risk of vertebral fractures and to increase bone mineral density.\textsuperscript{8,46-49}

Raloxifene and bazedoxifene are oral tablets taken once a day. Common side effects of raloxifene and bazedoxifene are hot flushes, leg cramps, peripheral edema, and vasodilation.\textsuperscript{38} The use of these drugs has also been associated with an increased risk for venous thromboembolic events (VTE) such as deep vein thrombosis and pulmonary embolism.\textsuperscript{38} Several clinical trials of raloxifene noted that the increase in absolute risk for VTE was 1.2 - 1.8.\textsuperscript{50} Clinical trials of bazedoxifene did not report VTE as an adverse effect of treatment\textsuperscript{51-53} or the incidence of VTE was no greater in patients treated with bazedoxifene than in patients treated with placebo.\textsuperscript{54}

\textit{RANKL inhibitor}
Denosumab (Prolia®) is a RANKL inhibitor that has FDA approval for the treatment of post-menopausal women who are at high risk for fractures, and for the treatment of osteoporosis (to increase bone mass) in men who are at high risk for osteoporosis.

Denosumab is a monoclonal antibody that has a binding affinity to RANKL. RANKL is found on the surface of osteoclasts, and denosumab prevents RANKL from binding to and activating its receptor, RANK (Receptor Activator of Nuclear Factor κ B). This action inhibits osteoclast activity, formation, and survival and by doing so decreases bone resorption. The approved dose of Prolia® is 60 mg, given subcutaneously, every six months.

Denosumab has been proven in large clinical trials to significantly reduce the risk of hip, vertebral, and non-vertebral fractures and to significantly increase bone mineral density, as well. Denosumab has been described as safe and well tolerated, with no significant difference between denosumab and placebo or biphosphonates in terms of the risk of adverse effects. However, serious adverse effects have been associated with the use of denosumab. Some of these, such as hypocalcemia, osteonecrosis of the jaw, and atypical femoral fractures, are rare or relatively rare and the association between the drug and these complications is tenuous. But other adverse effects, such as serious infections of the skin and upper respiratory tract and urinary tract infections, are significantly more common in patients taking denosumab than in those who are not.
Because of the potential for serious adverse effects, the FDA requires that all patients who are prescribed Prolia® be given an FDA-approved patient medication guide. This medication guide warns patients that Prolia® may cause hip fractures, hypocalcemia, osteonecrosis of the jaw, serious allergic reactions, serious infections, skin problems, and, severe bone, joint, or muscle pain. The FDA-approved patient medication guide can be viewed at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM214385.pdf.

*Parathyroid hormone*

Parathyroid hormone is secreted by the parathyroid gland, and its primary function is to increase serum levels of calcium. Teriparatide (Forteo®) is a synthetic form of parathyrtoid hormone, and it is approved by the FDA for the treatment of osteoporosis in postmenopausal women and men who are at high risk for fracture. Teriparatide stimulates osteoblast function, increases the gastrointestinal calcium absorption, and increases renal tubular reabsorption of calcium, all of which act to increase new bone formation.\(^{60,61}\) Teriparatide increases bone mineral density and bone mass,\(^{62}\) and it has been shown to significantly reduce the risk of vertebral and non-vertebral fractures.\(^{8,63,64}\) Forteo® is given subcutaneously at a dose of 20 mg once a day.

Common side effects of Forteo® are arthralgia, nausea, and pain.\(^ {60}\) The FDA requires that all patients who are prescribed Forteo® be given an FDA-approved patient medication guide. The FDA-approved guide and the Forteo® package insert both note that during drug testing of Forteo® some rats developed osteosarcoma, and osteosarcoma has rarely been reported in
patients who took the drug. The package insert warns that the relevance of this animal study finding is unclear for humans, but that Forteo® should not be prescribed for patients who have an increased risk for osteosarcoma. The patient medication guide can be viewed at: http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088604.pdf.

*Estrogen hormone therapy*

The FDA has approved estrogen products for the prevention of osteoporosis. Estrogen has been shown to significantly reduce the risk of vertebral fractures and hip fractures. However, the FDA also recommends that because of an increased use of breast cancer, coronary artery disease, stroke, and VTE that the lowest effective dose of estrogen should be used for the shortest possible time, and, if possible, other drugs should be used before estrogen.

Estrogen products are available as tablets and transdermal patches. There are many estrogen and estrogen derivatives that are in use, *i.e.*, Premarin®, Estrace®, Femhrt®, Prefest®. A review of the common side effects associated with all of these drugs is not practical for this study module, and may be found in any prescription drug guide.

*Other drugs, vitamins, and minerals*

There are other drugs that are used for the prevention and/or treatment of osteoporosis, but the ones discussed in this study module are the ones with FDA approval for these purposes. The role of vitamin D supplementation in the prevention and treatment of osteoporosis is somewhat controversial.
Maintaining adequate dietary intake of vitamin D is universally recommended in treatment recommendations for osteoporosis. However, as mentioned earlier, there is no unequivocal evidence that increasing vitamin D levels helps to reduce the risk of fractures or to prevent bone loss.\textsuperscript{13-15} In addition, the amount of vitamin D that is needed for the prevention and treatment of osteoporosis is not known,\textsuperscript{11,66} and it is not clear that vitamin D supplementation is effective at preventing falls.\textsuperscript{67}

The role of calcium supplementation in osteoporosis involves similar issues. Patients who have osteoporosis or at risk for developing osteoporosis are advised to make sure they have an adequate dietary intake of calcium, but recent meta-analyses of the literature do not show that calcium supplementation has a significant effect for preventing fractures.\textsuperscript{10}

**Drug duration and drug holidays**

The optimal duration of drug therapy for the treatment of osteoporosis is not known, and after a certain number of years (\textit{i.e.}, five years for denosumab) there is no information about the effectiveness and the safety of the medications used to treat osteoporosis.\textsuperscript{38} Rare complications of osteoporosis drug therapy such as atypical fractures of the femur and osteonecrosis of the jaw, appear to become more common when the duration of drug use is prolonged,\textsuperscript{38} but there is no data that can be used to decide when the risks of drug therapy outweigh the benefits.\textsuperscript{8}

Since the therapeutic effectiveness of some of the drugs, specifically the bisphosphonates, have been shown to extend for several years after they have been discontinued, the idea of a “drug holiday” has been mentioned in the medical literature: stopping drug therapy to avoid complications while
retaining the medication’s therapeutic effects.\textsuperscript{27,28} However, there is essentially no data that can be used to decide when and for whom a drug holiday might be helpful,\textsuperscript{27} and the NOF 2014 guidelines simply note that treatment duration decisions should be made individually and that, after three to five years of drug therapy, a comprehensive risk assessment should be done.\textsuperscript{8}

**The Nurse’s Role: Caring For Patients With Osteoporosis**

Nurses have a key role in caring for the patient with osteoporosis during various stages of disease progression. Patients are at risk of fall and injury and require ongoing monitoring and education of their treatment plan, medications and health prevention strategies.

**Patient Monitoring**

Osteoporosis and fractures caused by osteoporosis can be prevented by the proper attention to diet, exercise, reduction and/or elimination of factors that increase the risk of a fall, smoking cessation and moderate use of alcohol, medications, and periodic assessment of the patient’s bone mineral density and clinical condition. The patient who has osteoporosis should be given a diet plan and an exercise program, and risk factors for falls should be identified and eliminated or modified.

The patient’s medication regimen should be periodically reviewed, the height should be measured every year (a decrease in height could indicate the presence of a vertebral fracture), and bone mineral density should be checked by DXA every two years\textsuperscript{8} or when clinically indicated. The prognosis for someone with osteoporosis is good, especially if screening catches the
disease early. Many of the complications of osteoporosis are related to fracture, and if treatment can prevent fracture then the prognosis is good.

**Patient Education**

A primary role of the nurse is educating the patient. Nurses should teach patients who have osteoporosis or are at risk for osteoporosis about lifestyle changes to maximize bone health. Additionally, nurses should encourage all patients to perform weight bearing exercise, get adequate calcium and vitamin D, avoid smoking and excessive alcohol, and get some sun exposure on the face and hands most days of the week.

Nurses need to understand the screening guidelines and to recommend screening to appropriate patients. Safety precautions to prevent falls are critical in patients with osteoporosis. Prevention of falls is important because patients with low bone mass are at high risk for fracture.

The table below lists fall prevention strategies that nurses may implement.
FALL PREVENTION STRATEGIES

- Assure adequate vision – have patients at risk see an eye doctor
- Have occupational therapy perform a home safety evaluation
- Assure that the home is free of clutter
- Assure that the home has adequate lighting
- Assure surfaces in the home are non-skid (floors, mats and shower mats)
- Make sure the patient has good shoes
- Have the patient perform balance exercises, such as Tia Chi
- Encourage regular exercise
- Evaluate patient medications as some medications increase the risk for falls such as anti-anxiety medications, blood pressure medications, pain medications and sleeping pills. If you suspect a medication is contributing to falls speak with the doctor.
- Encourage the patient to have an evaluation with his/her primary care provider to assure all medical conditions are well controlled. Uncontrolled health problems increase the risk of falls.
- Recommend assistive devices if appropriate

Helping patients understand osteoporosis and their risk for disease is a major role of the nurse. Patients who speak intelligently to their doctor will receive better care. Below is a list of questions that nurses should encourage each patient to discuss with their doctor to help them fully understand their disease.

- Do I have any risk factors for osteoporosis?
- What is my T-score?
- What caused this disease in me?
What are my risk factors for this disease?
When will I have my next DEXA scan?
Could I benefit from medication to increase my bone density?
What are the side effects of the medications that are being prescribed for me?
What can I do to reduce my risk of falls?
How much calcium/vitamin D should I take in a day?
What type of exercise should I do? How often should I exercise?
Do any of my health problems put me at risk for falls?
Do any of my medications put me at risk for falls?

The following two case studies help to elucidate many of the key aspects of diagnosis and treatment that the nurse may encounter when caring for individuals with osteoporosis.

**Case Study 1**

A 65-year-old post-menopausal female presents to her doctor for an annual exam. She is 5’ 4” and weighs 122 pounds. She is afflicted with mild osteoarthritis of both of her knees, hypertension and mild depression. Her current medications include a multivitamin daily, hydrochlorothiazide 12.5 mg a day and sertraline 50 mg a day. She averages one alcoholic beverage a day and does not currently smoke, but quit smoking 10 years ago and has a 20 pack-year history. She does not do any formal exercise, but reports being quite active cleaning houses, as she owns a house cleaning business. She has no family history of osteoporosis, her mother never had a fracture and she never had a fracture in her life.
Her doctor recommends that she be screened for osteoporosis by dual-energy x-ray absorptiometry. Her T-score at her hip is – 2.6 and -1.8 at her spine. When her information was placed into the FRAX calculator she came up with a risk of a major osteoporotic fracture of 9.8% and the risk of hip fracture of 2.0%.

She is seen back in her primary care doctor’s office in one week to follow up on her abnormal DEXA scan. The doctor gives her a diagnosis of osteoporosis based on her T-score being below -2.5. The doctor discusses the following points.

1. Start alendronate at 70 mg once a week – she is a candidate for therapy because she has a T score at her hip of -2.6. Her kidney function is within normal limits for her age. Renal failure is a reason to not use bisphosphonates.

2. Routine blood work ruled out any disease of the thyroid or parathyroid. Alkaline phosphatase, serum phosphate and calcium and vitamin D levels were normal.

3. She is encouraged to start a calcium supplement. The doctor recommends 500 mg twice a day in addition to a couple servings of dairy each day such as milk, cheese or yogurt.

4. Add a vitamin D supplement to get 800 IU of vitamin D each day.

5. The doctor recommended sunlight on the face and hands 2-3 times a week to maximize vitamin D levels.

6. She was encouraged to engage in weight bearing exercise 5 times a week.
7. She was encouraged to perform upper body weight training three times a week to maximize bone strength in the upper body.

8. She is to have a repeat DEXA scan in 2 years to assess the efficacy of therapy.

Case Study 2

A 72-year-old female post-menopausal female went to her primary care physician because she had been having low back pain for approximately five weeks. The patient has a medical history of depression, GERD, hypertension and osteoarthritis. She is currently prescribed lisinopril, HCTZ, celecoxib, omeprazole, and paroxetine.

The patient has been smoking cigarettes for over 40 years, she does not exercise, and she only leaves the house for brief periods, several days week. According to the patient, walking is painful because of the osteoarthritis she has in her hips, and she is worried that she may fall.

The patient admits that her diet is largely prepared foods and she does not drink milk or eat other calcium-containing foods. She also drinks at least six cups of coffee a day. She denies recent trauma to her lower back or a fall, but does report that she first noticed the lower back pain after she bent over and moved a heavy chair from one part of her living room to another. The patient is 62 inches tall and weighs 105 pounds. The area of the pain is non-tender to palpation and there are no areas of swelling or ecchymosis.
A plain x-ray of the lumbar spine reveals a fracture, and based on the patient’s age, gender, post-menopausal status, and the presence of several risk factors, the physician makes a provisional diagnosis of osteoporosis. The diagnosis is confirmed by a DEXA scan result of -3.0. The results of the laboratory tests the physician ordered are normal except for a vitamin D level of 20, with the low normal being 30. The physician makes the following recommendations.

1. Calcium supplementation, 1000 mg a day.
2. Vitamin D supplementation, 800 IU a day.
3. Begin a smoking cessation program.
4. Get at least 30 minutes of direct exposure to the sun, three to five days a week.
5. Decrease coffee intake to three or less cups a day.
6. Alendronate, 10 mg, daily.
7. Physical therapy consultation for instruction on weight-bearing exercises; body mechanics for avoiding stress that may cause fractures; assessment for the need of an assistive device such as a cane or walker; and, stretching exercises.
8. Psychotherapy consult (the intention being to possibly lessen dependence on paroxetine as the SSRIs are known to be a risk factor for osteoporosis).
Case Study 3

A fifty-four year old female presents to her doctor’s office because of irregular periods and hot flashes. The patient is an advertising executive who lives a very stressful life and works 60-70 hours a week. She has no significant medical conditions and takes no regular medications. She does not engage in regular exercise, eats a lot of fast food and smokes about 2 packs of cigarettes per week. She is 63 inches tall with a body weight of 146 pounds. She reports that her job keeps her locked up inside most of the day. She drinks about 7-10 alcoholic drinks per week, mostly on the weekend and consumes about six cups of coffee each day.

Her mother currently lives in a nursing home due to immobility secondary to a hip that she broke 10 years ago. She is unsure if her mother has been diagnosed with osteoporosis. She reports no personal history of fracture. The doctor performs a complete history, physical exam, selected blood work and a DEXA scan. The history and physical exam were without significant abnormality except for irregular periods, hot flashes and a slight increase in body mass index. Blood work showed hormonal levels that suggest perimenopause. The other abnormality on laboratory evaluation was a low vitamin D level of 14 ng/dl. The remaining blood work was normal.

Her DEXA scan shows a T-score of -1.4 at the hip and -1.4 at the spine. Her FRAX score shows a 10-year risk for a major osteoporotic fracture and risk for a hip fracture at 17 percent and 1.6 percent, respectively. The doctor diagnoses her with osteopenia and opts to not treat her with pharmacological agents to treat low bone mass. The physician discusses the possible short-term benefits of hormone replacement therapy, but after the
negative effects are discussed with the patient, they decide against hormone replacement. Her doctor makes the following recommendations.

1. Engage in regular weight bearing exercise at least three times a week.
2. Engage in weight training exercise at least twice a week.
3. Take vitamin D 50,000 IU once a week for 8 weeks and follow up after treatment for a repeat blood test.
4. Get 10-15 minutes of sunlight exposure at least twice a week on the face and arms to increase the vitamin D level. Her low vitamin D level was partly caused by her lack of sunlight exposure.
5. Take 500 mg of calcium supplementation twice a day and consume a couple servings of dairy each day such as milk, cheese or yogurt.
6. Quit smoking because smoking may contribute to bone loss as well as lead to many other health problems.
7. Reduce binge drinking. She was counseled about the negative effects of alcohol on bone as well as overall health.
8. Reduce coffee intake. She was encouraged to switch to green tea. If coffee is to be continued she is encouraged to cut back and substitute decaffeinated coffee.
9. She was counseled on stress management and healthy eating. She was offered an appointment with a stress management specialist and dietitian.
10. She was encouraged to have a repeat DEXA scan in two years to assess for progression of her osteopenia.
Summary

Osteoporosis is a significant public health problem, and as the population continues to age it is likely that the number of people who have, or are at risk for developing osteoporosis, will increase. Although some degree of bone loss is an inevitable part of aging, identification of those at risk and preventive measures are critical in the management of the disease.

Risk factors identified in this study module for developing osteoporosis are either non-modifiable (i.e., age, gender) or modifiable (i.e., use of alcohol, level of activity, cigarette smoking). Post-menopausal women are at high risk for developing osteoporosis, but elderly men are at risk, as well. The disease is clinically silent. Most cases are identified after the patient has suffered a fracture or by a screening test.

Fractures are the most serious complication of osteoporosis. Screening for osteoporosis should be done in all women age 65 and older, all men age 70 and older, and, postmenopausal women and men above age 50-69, based on risk factor profile. The preferred method of measuring bone mineral density and diagnosing osteoporosis is dual-energy X-ray absorptiometry (DEXA).

The treatment and prevention of osteoporosis is done by attention to diet, regular weight-bearing exercise, modification of harmful life style habits, elimination and/or reduction of fall risk factors, and medications that prevent bone loss or increase bone formation. Bisphosphonates have been proven to prevent fractures in patients who have osteoporosis and evidence exists that they also decrease morbidity and mortality.
The FDA has approved bisphosphonates to treat osteoporosis as well as other medications used to treat osteoporosis such as calcitonin, estrogen agonist/antagonist, estrogens or hormone therapy, parathyroid hormone and RANKL inhibitor. Among these medications, bisphosphonate derivatives are considered to be the first-line therapy for the treatment of osteoporosis, and the FDA has approved bisphosphonates for the prevention or treatment of osteoporosis, such as alendronate (Fosamax®), ibandronate (Boniva®) risedronate (Actonel®), and zolendronic acid (Reclast®). These medications act to inhibit bone resorption by inhibiting the action of osteoclasts and osteoclast precursors.

Common side effects and significant risks exist with the use of bisphosphonates. High doses are nephrotoxic and approximately 50% of bisphosphonates are excreted unchanged therefore renal impairment leads to drug accumulation and toxicity. Prior to taking bisphosphonates, the patient’s glomerular filtration rate should be evaluated for levels < 30 - 35 mL/minute, which would require the medication be avoided or administered with extreme caution under consultation with a nephrologist if clinically indicated.

Serious complications associated with bisphosphonate therapy that have been identified include osteonecrosis of the jaw, atypical fracture of the femur, atrial fibrillation, and esophageal cancer. To avoid damage to the esophagus the patient should follow recommended administration guidelines, such as remaining in an upright position after taking the bisphosphonate medication on an empty stomach in the morning.
There are indications that the prolonged use of medications used to treat osteoporosis may increase the risk of serious complications, and some clinicians have suggested using drug holidays to lessen the chances of serious adverse effects. This issue is unresolved, and the NOF simply recommends a risk assessment after three to five of drug therapy and advises that the benefits and risks of long-term drug therapy for osteoporosis must be evaluated on a case-by-case basis.

Importantly, nurses play a key role in the ongoing care, close follow-up and education of patients with osteoporosis to best manage symptoms, to avoid falls and fractures, and to promote preventive strategies.

Please take time to help NurseCe4Less.com course planners evaluate the nursing knowledge needs met by completing the self-assessment of Knowledge Questions after reading the article, and providing feedback in the online course evaluation.

Completing the study questions is optional and is NOT a course requirement.
1. Approximately 80% of the cases of osteoporosis in the United States occur in
   a. women
   b. African Americans
   c. men
   d. young adults

2. Osteoporosis is caused by a disruption in
   a. calcium absorption
   b. blood supply to the bones
   c. bone remodeling
   d. the nerve fibers of the bones

3. Post-menopausal osteoporosis is primarily caused by
   a. an increase in serum parathyroid hormone levels
   b. decreased production of estrogen
   c. decreased intake and absorption of vitamin D
   d. decreased blood supply to the bones

4. Age-related osteoporosis is primarily caused by
   a. decreased exposure to sunlight
   b. decreased production of estrogen and testosterone
   c. increased renal excretion of calcium and vitamin D
   d. a decrease in the number of functioning osteoblasts

5. Lifestyle risk factors for the development of osteoporosis include
   a. cigarette smoking and excessive use of alcohol
   b. male gender and atherosclerosis
   c. chronic kidney disease and inadequate intake of calcium
   d. African American ethnicity and over-exposure to sunlight
6. **Risk factors for the development of osteoporosis include**
   a. advanced age and liver disease
   b. use of anticonvulsant medications and high-body mass index
   c. female gender and sedentary life style
   d. abstinence from alcohol and low body-mass index

7. **The most important complication of osteoporosis is**
   a. renal impairment
   b. fractures
   c. malabsorption syndrome
   d. joint contractures

8. **Which of these is considered first-line treatment for osteoporosis?**
   a. Calcitonin
   b. Parathyroid hormone
   c. Vitamin D and calcium supplementation
   d. Biphosphonates

9. **Patients who are prescribed a biphosphonate should be instructed to**
   a. take it in the morning on an empty stomach and remain upright for 30-60 minutes
   b. take it in the evening with a fatty food
   c. take it with milk and remain upright for 30-60 minutes
   d. take it with water only and immediately before going to sleep

10. **True or false: Osteoporosis can be prevented but established osteoporosis cannot be reversed**
    a. True
    b. False
Correct Answers:

1. A
2. C
3. B
4. D
5. A
6. C
7. B
8. D
9. A
10. A

References Section

The reference section of in-text citations include published works intended as helpful material for further reading. Unpublished works and personal communications are not included in this section, although may appear within the study text.


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