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PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

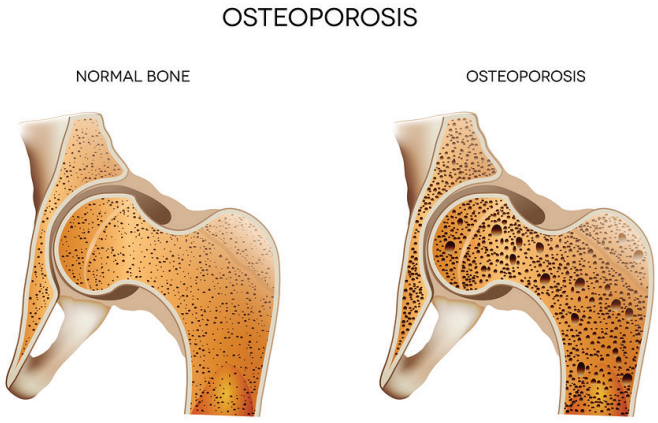
"Update: Osteoporosis--Pharmacy Perspective"

January 2015

Osteoporosis is a condition that impacts a growing percentage of the public. Our goals in this lesson are to review this topic, with emphasis on causes & treatment:

Pharmacists will be able to:

1. Define 'osteoporosis' & comment upon its incidence.
2. Describe the process of bone modeling & repair.
3. List risk factors associated with osteoporosis.
4. Compare the methods for diagnosing osteoporosis.
5. Discuss treatment & prevention of osteoporosis.



Technicians will be able to:

1. Define 'osteoporosis.'
2. Differentiate between 'compact' & 'spongy' bones.
3. List risk factors associated with osteoporosis.
4. List drugs that are used for treating osteoporosis.

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INTRODUCTION

Osteoporosis (Greek meaning porous bones) is an insidious, progressive, systemic, skeletal disease that results in reduction of bone density and mass per unit volume. Such change causes the bones to become porous, thin, weak, brittle, fragile and vulnerable to increased susceptibility to breaks or fractures. This occurs as a result of a decrease in **Bone Mineral Density or BMD**. The consequence is micro-architectural deterioration. The sufferer may not be aware of this silent disease until a fracture occurs. A simple fall, carrying moderately heavy objects, getting in and out of a car or bath tub, coughing or sneezing, all could initiate a fracture. Osteoporosis is the most common bone disease. Even though older women and men experience bone loss with advancing age, younger patients may experience bone absorption or loss, if bones did not reach optimal growth during childhood and adolescence.

Osteoporosis may be classified as **primary, secondary, or involuntary**. **Primary** osteoporosis commonly develops in postmenopausal women, mainly as a result of diminished estrogen production. **Secondary** osteoporosis occurs as a consequence of intake of medications or the presence of a systemic disease. Drugs such as aluminum compounds, anticoagulants, cytotoxics, glucocorticoids, adrenocorticotropics, immunosuppressants, lithium, long-acting parenteral progesterone and thyroxin may precipitate secondary osteoporosis. Likewise, diseases such as anorexia nervosa, hyperthyroidism, hypogonadism, malnutrition and malabsorption syndromes are associated with increased risk of secondary osteoporosis. About 30 to 50% of osteoporosic cases result from secondary causes. **Involuntary** osteoporosis occurs with aging.

BONE STRUCTURE

There are two basic types of bone (osseous) tissue: **compact** and **spongy**.

Compact (cortical, lamellar) bones appear dense and smooth to the naked eye, but microscopic examination reveals the presence of tiny plates of thin osseous tissue organized around compartments that contain nerves and blood vessels.

Spongy (trabecular, cancellous) bones are porous and consist of honeycombs of vertical and horizontal, needle-like bones filled with red marrow and fat. All bones consist of both types of bones with the spongy trabecular tissue surrounded by a thin shell of dense cortical tissue. The vertebrae, the pelvis, and proximal femur are composed mostly of spongy tissue that is more prone to osteoporosic changes and bone mass loss than the compact cortical tissue. This accounts for the fact that osteoporosis occurs earlier and far more severely in the spine and pelvis than other parts of the skeleton.

Chemically, bones consist of about 50% water and the remainder is solid substances made of organic and inorganic compounds. The organic compounds consist chiefly of cells such as osteoblasts, osteocytes, and osteoclasts. The osteoblasts produce organic materials such as collagen, proteoglycans, and glycoprotein that are hardened by inorganic minerals such as calcium phosphate, calcium hydroxide, calcium carbonate, fluoride, sodium, potassium and manganese. Osteoclasts are responsible for bone resorption.

Bone tissue participates in three major activities. These are: **1) Modeling** which is a process that deals with establishing the characteristic shape of each bone; **2) Repair** which is the regenerative response (self-repair) of a bone to the pressure of a fracture; and **3) Remodeling** which is an ever-present cycle of destruction (resorption, breakdown, removal, and renewal).

Renewal is formation and replacement of deposits of bone tissue that is coordinated by an independent packet of osteoblasts and osteoclasts referred to as "bone remodeling units." In a healthy adult skeleton the rate of formation basically equals the rate of resorption, and thus no bone loss. However, the remodeling process does not occur uniformly. There are certain bones such as the hip (distal portion of the femur) that are replaced every four to six months, whereas the shaft of this bone undergoes remodeling at a slower rate. The process of bone resorption, which is the first step of bone remodeling, is carried out by the bone remodeling units that may be activated by either hormonal or physical signals. These signals cause the inactive cells on the surface of the bone to be replaced by phagocytes that form clusters and eventually fuse to become multinucleated osteoclasts, each of which, over a period of about two weeks, excavates a resorption microscopic cavity on the surface of cancellous bones or tunnel-like structures within the cortical bone. The process of bone renewal takes place when a local release of a chemical factor attracts bone-building osteoblasts into the resorption cavity where they begin to replace the missing portion of the bone by first secreting collagen matrix, followed by mineral (calcium and phosphorous) deposition. Remodeling is completed within 8 – 12 weeks after the onset of the cycle. Because bone replacement by the remodeling cycle is not entirely efficient, a small bone deficit exists at the end of each cycle. This deficit accounts for age-related bone mass loss.

Bone remodeling is regulated mainly by negative feedback hormonal mechanisms involving parathyroid hormone (PTH) and calcitonin (released by the thyroid gland). Low calcium blood level acts as a stimulus in PTH release which causes stimulation of the activity of the osteoclasts, and subsequent release of calcium ions into circulation. The resultant elevation of calcium blood level acts as a trigger for ending PTH release and in the release of calcitonin which inhibits bone resorption and enhances bone replacement by causing deposition of blood calcium back into the bone matrix. The decline in calcium blood level signals the end of calcitonin release.

EPIDEMIOLOGY

Osteoporosis is prevalent worldwide and is considered a major public health problem that can contribute to morbidity, mortality and functional loss in the sufferers, particularly the elderly. It affects men and women of all races. However, whites and Asian postmenopausal women are at a higher risk. Presently it is estimated that there are more than 200 million individuals with osteoporosis worldwide. Its incidence will increase as life expectancy increases. About 30% of postmenopausal American women are osteoporosic. Moreover, about 50% of white women will have osteoporosic fractures during their life time, including 25% who will have spine deformity and 15% will experience hip fractures. Approximately half of women over age 50 will experience hip, wrist or vertebral fractures during their life time. About 40% of women and 15 - 30% of men over 50 years of age will suffer from one or more fractures as they become older. About 80% of the osteoporosis cases in the US are experienced by postmenopausal white women. African-American postmenopausal women have a higher BMD than that of white, non-Hispanic women, and have lower risk of hip fracture. Japanese women have a lower optimal BMD than white, non-Hispanic women, and are more vulnerable to hip fracture. The BMD of Hispanic-American women falls between white women and African-American women. A total of 1.5 million fractures occur in the US annually.

There are a number of reasons for low prevalence of osteoporosis in men. Women undergo a

phase of rapid bone loss at and immediately after menopause, while men show exponential increase in the development of osteoporosis about 5 – 10 years later. Women have a longer life expectancy than men. The older a women becomes, the more intense osteoporosis becomes. Most healthy men before the age of 50 have approximately 33% more bone mass than women of comparable age. Lastly, men have a tendency to be more active physically than women at the same age.

RISK FACTORS

There are a number of risk factors that increase the chance of developing osteoporosis. These factors include age, menopause, family history of menopause, thin frame, intake of drugs that interfere with calcium absorption, ethnicity, presence of low bone density, diet and lifestyle. Risk factors can be categorized as **fixed** or **modifiable**.

Fixed Risk Factors are those that a patient cannot change or avoid. Examples include age, gender, pre-or-post-menopause, family history, ethnicity, presence of diseases such as osteoarthritis, and hypogonadism in men. **Age**: about 90% of hip fractures occur in patients 50 years of age and older. Diminished BMD is a natural process that occurs as a result of aging. Even older individuals with normal BMD are more prone to fractures than younger people due to improper body mechanics. **Gender**: due to the diminished production of estrogen as women approach menopause, reduction in BMD may occur, resulting in osteoporosis. Estrogen plays an important role in the development of bones. During menopause, women (40 - 50%) are more likely to experience osteoporosic fracture than men (13 - 22%). **Heredity**: family history of bone fractures, especially the hip, is often related to increased incidence of fractures. **Prior fractures**: history of previous fractures increases the risk of occurrence of new fractures by an estimated 86% when compared to patients who have never had fractures or breaks. **Ethnicity**: as mentioned earlier, the incidence of osteoporosis and fractures of the hip and spine in whites and Asians is higher than that among African-Americans. **The long term use of the anti-inflammatory steroid glucocorticoids** can result in steroid-related reduction in bone density, leading to osteoporosis, higher fractures risk and slower repair. **Rheumatoid arthritis** can cause damage to the bones, rendering them fragile, weak and susceptible to fractures. **Hormone deficiency**: estrogen deficiency in women and androgen deficiency in men may lead to osteoporosis and increased risk of fractures.

Modifiable Risk Factors are lifestyle choices that can adversely affect bone health and ultimately diminish BMD. However, these risk factors can be modified or avoided. **Excessive alcohol consumption** can result in a 40% increase in sustaining osteoporosic fractures compared to people who consume alcohol in moderate quantities or no drinking at all. Adverse effects of alcohol include damage to bone forming cells and interference with parathyroid hormone that regulates calcium metabolism. **Other modifiable risk factors include: excessive consumption of caffeine, cigarette smoking, low body mass index, inadequate nutrition, in particular diet poor in calcium contents, vitamin D deficiency (vitamin D is required for calcium absorption from the intestine), anorexia, immobility, lack of exercise (sedentary life-style), visual impairment, loss of balance (90% of hip fractures result from falls).**

SIGNS AND SYMPTOMS

There are no signs and symptoms to this age-related disease. As indicated earlier, it is insidious in nature and is considered a silent disease. The patient will realize its presence only when fracture is experienced. Diagnostic tests can reveal the extent of bone deterioration.

DIAGNOSIS

Elevation of BMD will indicate the presence or absence of osteoporosis and the extent of its progress. Determining BMD is the most commonly used method in diagnosing osteoporosis. The NOF (National Osteoporosis Foundation) published a guideline to BMD testing in women:

- All women 65 years of age and older, regardless of the presence or absence of risk factors,
- Younger postmenopausal females, and
- Postmenopausal women who experienced fragility fractures to confirm diagnosis and determine disease severity.

For BMD testing in men, the World Health Organization (WHO) and the International Society of Clinical Densitometry recommended that men who experience low trauma fractures, exhibit radiographic osteopenia (low bone mass), suffer from hypogonadism and/or hypothyroidism, abuse alcohol, or take corticosteroids, should take the BMD test.

BMD measurement can confirm or rule out the presence of osteoporosis. The lower the BMD, the greater the severity of the disease and the higher the risk of fractures.

Measurement of BMD can be done at any skeletal site. However, hip BMD is the best predictor of hip fracture. Several techniques can be utilized for BMD measurement.

1. **Dual X-Ray Absorptiometry (DXA):** This technique can be employed for measuring BMD in the hip, wrist and spine. DXA emits a beam of X-ray photons that penetrate the bones to be tested. The test is safe and can be completed in a few minutes. It gives radiation exposure per site approximately one-tenth that of a standard chest x-ray. Central DXA usually provides definitive diagnosis.
2. **Peripheral Dual X-Ray Absorptiometry (p-DXA) and Simple-Energy X-Ray Absorptiometry (SXA):** This method measures bone density in the forearm, wrist, finger, and heel.
3. **Quantitative Computed Tomography (QCT):** QCT is capable of revealing signs of loss in both cortical and trabecular bones, especially in the spine.
4. **Peripheral QCT (pQCT):** This technique may be used to detect bone density in the periphery.
5. **Ultrasound Densitometry:** Ultrasound is used to evaluate bone density in the heel, tibia, patella or other peripheral sites. It is not as accurate as DXA or SXA.

OSTEOPOROSIS RELATED FRACTURES

Once a patient sustains a fracture, the risk factors for the occurrence of future fractures increases by about 86%, and they may occur in any part of the skeleton. However, the most common sites are those in the vertebrae (25%) such as in the thoracic area (mid-back) and lumbar spine (lower back), the hip (25%), the wrist (25%) and 25% in other parts of the skeleton. Individuals who experience spine fractures have a 2-3% increased risk of fractures in the hip and 1-4% increase of distal fractures.

Depending on severity, fractures may cause depression, hopelessness, loss of self-esteem, fear, anger, and frustration due to the presence of pain and lack of physical independence.

It has been estimated that the annual cost of osteoporosic fractures to the health care system in the US could reach $20 billion. The direct cost of a single hip fracture is estimated to be over $40,000.

Vertebral Fractures occur in one or more vertebrae. The most common sites take place in the thoracic area, lumbar spine, or at the thoracolumbar junction. These fractures usually occur as a result of sudden impact such as a car accident, a fall or a sport injury. The incidence of fractures in the spine is 4 times more common in men than in women. Vertebral fractures may result in neural damage causing weakness, pain, numbness and tingling as well as height loss, kyphosis (rounding of the back), and limited mobility.

Hip Fractures: The hip can be described as a ball and socket joint that contains ligaments and cartilage, allowing the upper leg to bend and rotate with relative stability. These fractures usually occur as a result of falls or impacts to the side of the hip. In a healthy, young person, such accidents may not cause fractures. However, in an elderly osteoporosic patient, whose bones are fragile and porous, such trauma (even simple flex and twist of one leg) may result in hip fracture. Complications may occur as a result of immobility, such as blood clots, bed sores, urinary tract infections and pneumonia.

Wrist Fractures: These are often the first sign to indicate the presences of osteoporosis. Patients who experience wrist fractures are advised to consult a physician for evaluation if osteoporosis is present.

MANAGEMENT OF OSTEOPOROSIS

Osteoporosis is a manageable and preventable disease. This can be achieved by using **medications**, and **changing lifestyle**.

Medications

As indicated earlier, bone is a living tissue that undergoes remodeling. Bone formation medications used in osteoporosis treatment are intended to: 1) slow bone resorption or loss (anti-absorptive) and 2) increase the rate of bone formation and maintaining bone density. That stated, there is no drug that can reverse an already established osteoporosis condition. The first-line of drugs is the **bisphosphonates such as alendronate, risedronate, ibandronate, zoledronate and denosumab**. The other drugs are **raloxifene**, and lastly **calcitonin**. The bisphosphonates act by binding to hydroxyapatite crystals on the bone surface resulting in inhibition of osteoclast activity, thereby inhibiting bone resorption, and increasing bone density.

Bisphosphonates

Alendronate: This drug may be given in a 5 mg daily dose for two years followed by 10 mg daily for the third year. To receive full benefits from alendronate, enough calcium and vitamin D should be given prior to the start of therapy in order to enhance bone development. It has been shown that alendronate increases spinal bone density and reduces the frequency of vertebral, wrist and hip fractures by about 48% over the three year period of therapy in patients with prior spine fractures, and about 48% over 3 years in patients without prior fractures. Adverse effects are mild and include dysphagia, GI disturbances, esophageal irritation, musculoskeletal aches, headaches, and dizziness. None of these symptoms typically necessitate discontinuation of treatment. Alendronate is not recommended for patients with

renal dysfunction, and should be used with caution in patients who suffer from active upper GI diseases. The drug must be taken with a full glass of water (no other liquid) at least one half-hour before breakfast. Taking the medication with meals or orange juice or coffee tends to reduce drug absorption. The patient should not lie down for at least one-half hour after administration to prevent esophageal ulcers.

Risedronate: This drug is administered orally in doses of 5 mg daily or 35 mgs weekly. It has been reported that risedronate reduces the incidences of spine fractures by 41 - 49% and non-spine fractures by 36% over 3 years in patients with a prior spine fracture. The adverse effects are similar to alendronate.

Ibandronate: The usual recommended dose is a 2.5 mg tablet once daily or 150 mg once every month. Both types of tablets should be taken in the morning on an empty stomach. Ibandronate must not be taken at bedtime. The tablet must be taken with a full glass of water and not with other liquids, such as tea, coffee, juice, milk, or carbonated beverages. Once taken, the patient must refrain from eating or drinking for one hour. Sitting or standing upright is recommended for at least one hour after intake. Misuse of the drug may cause damage to the esophagus.

Zolendronate is a third generation bisphosphonate, which in addition to being used to reduce bone resorption, it can be used to treat hypercalcemia, and cancer that metastasizes to the bones. This drug is administered by intravenous infusion over a period of 5 minutes. The administration may be conducted at home. Side effects include dizziness, headache, flu-symptoms, musculoskeletal pain, irregular heartbeat, jaw pain, and vision impairment. The drug is available in 4 mg vials.

Denosumab is a human IgG2 monoclonal antibody that was approved by the FDA in 2010 for use in postmenopausal osteoporosis. It is available in vials that contain 120 mg denosumab. Side effects include tingling around the mouth, fingers and toes, difficulty in breathing, fatigue, headache, diarrhea, nausea, urinary and respiratory infection, constipation and rash.

Raloxifene, even with the use of estrogen replacement therapy (ERT), is helpful in treating osteoporosis; yet this method of treatment is not recommended due to increased risk of development of cancer. Raloxifene, which is a selective estrogen receptor modulator (CERM), has been approved by the FDA for the treatment and prevention of osteoporosis in postmenopausal women. The drug is an osteoclastic inhibitor. Adverse effects include hot flashes, leg cramps, headache, imbalance, chest pain, and cough, and more importantly, it may cause blood clots in the legs, lungs or eyes, strokes, and teratogenicity.

Calcitonin is a naturally occurring hormone produced by the parafollicular cells of the thyroid gland. It regulates calcium blood levels, helps reduce bone loss in postmenopausal women, as well as in men, and counteracts parathyroid hormone (PTH).

Life Style Change

Since osteoporosis progression is gradual, preventive measures can start early in life. Healthy nutrition is of utmost importance for bone development and growth. This should be a lifelong process. The bones gradually increase in size and strength as individuals become older. However, optimal bone mass is usually reached in the third decade of life, at which time

cessation of linear growth takes place.

There are a number of life-style changes that are recommended to improve bone health.

1. Adequate intake of calcium and vitamin D is essential. It has been shown that a reduction in the incidence of fractures, as well as improvement of BMD, have occurred following adequate intake of calcium and vitamin D. This can be achieved through consumption of calcium rich food along with supplements.

2. Regular physical activities early in life may result in increased optimal bone mass. Weight-bearing exercises such as walking, jogging, tennis, and low-impact aerobics are advisable. Such exercise may lead to strengthening of the muscles and improvement of balance and, ultimately, reduction in falling and fractures. Precautions such as correction of impaired vision and hearing, improving environmental conditions at home, compliance with directions for use of medications that cause drowsiness and avoiding activities that exert undesirable pressure on the skeleton such as pushing, pulling, bending, and lifting are important steps that may lead to reduced falling.

3. Smoking cessation and refraining from excessive alcohol intake are helpful for enhancing healthy bones. Cigarette smoking may accelerate bone loss as a result of accelerated estrogen metabolism. Excessive alcohol consumption adversely affects bone health and balance.

SUMMARY

Osteoporosis is a common silent disease that affects mostly women. It is asymptomatic, and the patient realizes its presence once a bone fracture is sustained and tests show deterioration in the bone mass. Osteoporosis is preventable and treatable. This can be achieved by using antiosteoporosic drugs and changing lifestyle.

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1. Does the program meet the learning objectives?
   - Define osteoporosis YES NO
   - Describe process of bone modeling YES NO
   - List risk factors of osteoporosis YES NO
   - Compare methods of diagnosing osteoporosis YES NO
   - Discuss treatment of osteoporosis YES NO

2. Was the program independent & non-commercial YES NO

	Low Relevance						Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____
5. What did you like least about this lesson?_____

Please Mark the Correct Answer(s)

1. **Another name for cortical bone is:**
   A. Trabecular bone B. Spongy bone
   C. Lamellar bone D. Cancellous bone
2. **Which of these is responsible for bone resorption?**
   A. Osteocytes B. Osteoclasts
   C. Osteoblasts D. Proteoglycans
3. **Which statement is true about directions for use of alendronate?**
   A. The drug should only be used at bedtime
   B. The patient should refrain from taking liquids when taking this drug
   C. The patient should not lie down for at least half an hour after intake of drug
   D. The drug must be taken with or immediately after meals
4. **Which of the following is not considered a risk factor for osteoporosis?**
   A. Weight B. Gender
   C. Age D. Excessive alcohol consumption
5. **Which of the following statements is true about bone fractures?**
   A. Cost of osteoporosic fractures to healthcare system in the US is $40 billion annually
   B. Kyphosis occurs as result of wrist fractures
   C. Vertebral fractures account for 60% of total
   D. Spinal fractures are more common in men than women
6. **The bisphosphonates act as antiosteoporosic drugs by:**
   A. Acting as estrogen replacement
   B. Binding to hydroxyapatite crystals on bone surface thereby inhibiting osteoclast activity
   C. Enhancing absorption of calcium from the intestines
   D. Potentiating parathyroid hormone
7. **Which statement is false about the epidemiology of osteoporosis?**
   A. Osteoporosis affects only women
   B. Osteoporosis is most common among white & Asian women
   C. About 50% of white women will have an osteoporosic fracture in their lifetime
   D. A total of 1.5 million fractures occur in US annually
8. **Which of the following drugs is administered by injection?**
   A. Risedronate B. Ibandronate
   C. Alendronate D. Zelondronate
9. **Which statement is false about raloxifene?**
   A. Acts as a selective estrogen receptor modulator
   B. It is considered an osteoclastic inhibitor
   C. It possesses teratogenic activity
   D. It is human IgG2 monoclonal antibody
10. **Which of the following is not an adverse effect of alendronate?**
    A. Dysphagia B. Vision loss or impairment
    C. Esophageal irritation D. Headache

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Contributing Author
Farid Sadik, Dean Emeritus
University of South Carolina
College of Pharmacy
Columbia, SC
Adjunct Professor, Presbyterian College

Executive Editor
William J. Feinberg, RPh, MBA

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