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Osteoporosis Disease Management: What Every Orthopaedic Surgeon Should Know

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Introduction

According to recent information from the National Osteoporosis Foundation and the Office of the Surgeon General, osteoporosis is a major medical problem. The disease currently affects 8 million women and 2 million men in the United States. An additional 34 million Americans have low bone mass. Each year, an estimated 1.5 million individuals in the United States experience a fragility fracture secondary to osteoporosis, resulting in an annual cost of 18 billion dollars. With the rapidly aging U.S. population, the problem of osteoporosis is now reaching epidemic proportions. There are 75 million baby boomers entering the stage in their lives when they are most at risk for osteoporosis. One-half of all women and one-third of all men will sustain a fragility fracture during their lifetime.

There is a huge cost associated with osteoporosis in terms of morbidity, mortality, and the financial impact on society. The most devastating complication of osteoporosis is a hip fracture. According to the most recent statistics published in the United States Surgeon General’s 2004 report on osteoporosis, of the 325,000 patients who sustain a hip fracture each year, 25% will find it necessary to enter a nursing home, 50% will never reach their previous functional capacity, and 25% will die within the first year after the fracture. The first-year mortality rate after a hip fracture is almost twice as high in men as it is in women (30% compared with 17%). The mortality rate associated with osteoporosis-related fractures is greater than the rates associated with breast cancer and cervical cancer combined.

Only 20% of patients who have had a previous hip fracture or other fragility fracture receive treatment for osteoporosis. There are certainly many missed opportunities for fracture prevention.

Pathophysiology of Osteoporosis

To achieve a significant decrease in osteoporosis-related hip fractures, it is important to understand the pathophysiology of osteoporosis as well as the risk factors that are associated with hip fractures.

Osteoporosis is characterized by low bone mass and structural deterioration of bone tissue, which leads to bone fragility and an increased susceptibility to fractures. Bone strength is related to bone density as well as changes in the micro-architecture of bone. The micro-architecture of bone is a poorly understood concept and is currently very difficult to measure without a biopsy. A dual x-ray absorptiometry scan provides information about bone density but does not provide any information about the micro-architecture of the bone. As bone strength decreases as a result of changes in bone density and/or changes in bone micro-architecture, the risk of fracture increases.

Bone remodeling is a combination of resorption and formation. With osteoporosis, there is a net loss of bone as well as a change in the micro-architecture of the bone. It is important to understand the factors that contribute to normal and abnormal remodeling of bone.

Calcium

Ninety-nine percent of the total calcium in the human body is stored in the bones. In addition to serving as a reservoir for the calcium needs of the body, stored calcium also acts as a bone strengthener. The small amount of calcium that circulates outside of bone plays a crucial role in muscle and nerve function. As serum calcium levels drop, bone resorption increases. Calcium absorption is significantly improved when the circulating levels of vitamin D are adequate.

Vitamin D

Even though it is called a vitamin, vitamin D acts more like a hormone in that it helps to increase calcium absorption and decrease calcium excretion. Vitamin D can be synthesized in the skin when the skin is exposed to ultraviolet-B rays from...
sunlight. A five to ten-minute exposure of sunlight to the unprotected arms and legs results in the production of 3000 IU of vitamin D\textsuperscript{18}. Proper intake of calcium and vitamin D may decrease fracture rates by up to 25% by maintaining good bone health\textsuperscript{19}. Vitamin D has been shown to decrease the types of falls that are often associated with fragility fractures\textsuperscript{20}.

Parathyroid Hormone
Parathyroid hormone plays a crucial role in helping to maintain calcium homeostasis. At physiologic levels, parathyroid hormone acts at the level of the osteoclast to increase bone resorption and it also acts in the gut to help assist in calcium absorption. At pharmacologic levels, parathyroid hormone stimulates osteoblasts to increase bone formation. Low vitamin-D levels may cause secondary hyperparathyroidism and a resultant increase in bone resorption\textsuperscript{7}.

Estrogen
Estrogen suppresses osteoclast activity in women and, surprisingly, also in men. The decrease in estrogen at the time of menopause leads to a rapid loss of bone mineral density\textsuperscript{19}.

Testosterone
Testosterone helps osteoblasts to form bone. Men on medications that suppress testosterone may experience a >4% drop in bone mineral density per year\textsuperscript{21}.

Secondary Causes of Osteoporosis
It is vital not to forget all the secondary causes of osteoporosis, such as primary hyperparathyroidism or tumors, when bone loss has been detected\textsuperscript{22}.

Laboratory Tests
There is no established set of laboratory tests for the routine evaluation of osteoporosis. Prior to the initiation of treatment, however, laboratory tests can be used to identify low blood calcium levels, vitamin-D deficiencies, and renal problems.

The following common routine laboratory tests may be helpful in the diagnosis and management of osteoporosis\textsuperscript{2}:

- **Serum calcium level.** This level is usually normal in patients with osteoporosis but may be elevated in patients with other bone diseases.
- **25-hydroxyvitamin-D level.** Deficiencies may lead to decreased calcium absorption. Vitamin-D deficiency is extremely common in elderly persons.
- **Complete blood-cell count.** Determination of the complete blood-cell count can be helpful in checking for secondary osteoporosis.
- **Twenty-four-hour urine calcium level.** The urine calcium level can be measured to check for hyperexcretion of calcium.
- **Parathyroid hormone level.** This level can be measured to screen for hyperparathyroidism.
- **Testosterone level.** The testosterone level can be measured to check for testosterone deficiencies in men.

- **Protein electrophoresis.** This test can aid in the identification of multiple myeloma.
- **Thyroid function tests.** The measurement of thyroid function can be helpful in screening for thyroid disease.

Risk Factors for Osteoporosis
There are modifiable and nonmodifiable risk factors for osteoporosis and fragility fractures that should be considered in all patients\textsuperscript{3}.

The nonmodifiable risk factors for osteoporosis fractures\textsuperscript{2} include the following:

- **The genetic profile.** In the future, there may be a potential for treatment with gene suppression or manipulation.
- **History of fracture in a first-degree relative.** This may be related to the genetic profile.
- **Female sex.** Compared with men, women have twice the risk of sustaining a fragility fracture.
- **Advanced age.** The risk of a hip fracture doubles every five years past seventy years of age.
- **Caucasian race.** Compared with Blacks, Caucasians have twice the risk of sustaining a fragility fracture.

The modifiable risk factors for osteoporosis fractures\textsuperscript{2} include the following:

- **Currently smoking cigarettes**
- **Low body weight** (<127 lb [57.6 kg] in women and <154 lb [69.9 kg] in men) or low body mass index (<20 in women and <25 in men)
- **Low calcium intake and low vitamin-D intake.** A single multivitamin tablet a day does not provide enough calcium or vitamin D.
- **Excessive alcohol intake**
- **Recurrent falls**
- **Poor physical activity**
- **Poor health or being frail**
- **Estrogen deficiency.** Early menopause or surgical menopause increases the risk of sustaining a fragility fracture.

Osteoporosis and Fracture Prevention and/or Treatment Medications

**Calcium and Vitamin D**

**Calcium:** Depending on a patient’s age, the daily calcium requirement varies. For patients who are more than fifty years of age, 1200 mg of calcium per day is recommended\textsuperscript{4}.

**Vitamin D:** Over the past several years, the recommended daily dose of vitamin D has increased. The newest recommendations suggest that 1000 IU of vitamin D is needed daily\textsuperscript{4}.

**Antiresorptive Agents**

**Oral bisphosphonate:** Bisphosphonates are considered the mainstay of preventative prescription treatment for patients with osteoporosis. Most patients with osteoporosis now take a generic bisphosphonate medication once a week. Bisphosphonates
should be used with caution in patients with chronic kidney disease and a reduced glomerular filtration rate. Bisphosphonates are not recommended in women of childbearing age who are not using adequate contraception. Bisphosphonates can decrease the hip fracture rate of a patient by as much as 50%.

**Intravenous bisphosphonates:** For patients who cannot tolerate oral bisphosphonates, an alternative is an annual intravenous injection of a long-acting bisphosphonate. This usually requires a ten to fifteen-minute infusion. A recent study showed a 25% decrease in mortality in a group of hip fracture patients who were given an intravenous dose of bisphosphonate shortly after the hip fracture.

**Estrogen:** The U.S. Food and Drug Administration guidelines regarding estrogen state that estrogen may be considered for use in the prevention of osteoporosis but not for use in the treatment of that disease. Women taking estrogen have a 35% lower rate of fracture than women who have stopped taking estrogen.

**Selective estrogen receptor modulators:** Selective estrogen receptor modulators act on bone by binding to estrogen receptors. This type of medication should be used in women who are at low risk for thrombotic complications.

**Calcitonin:** Calcitonin decreases calcium mobilization from bone by decreasing osteoclastic activation. Calcitonin has also been shown to decrease the pain associated with compression fractures of the spine.

**Anabolic Agents**

**Parathyroid hormone:** Unlike the antiresorptive agents listed above, parathyroid hormone drastically stimulates the overall formation of bone. It can be taken for a period of no longer than two years because of the risk of the development of bone tumors. Parathyroid hormone should not be used in patients who are at high risk of the development of osteosarcomas, such as patients who have Paget disease or who have undergone prior bone radiation.

**Risk of Treatment**

**Bisphosphonates and Osteonecrosis of the Jaw**

Osteonecrosis of the jaw (mandible) is a very rare complication in patients receiving oral and, more commonly, intravenous bisphosphonates. The risk has been estimated to be between one in 10,000 and less than one in 100,000 patient-treatment years. The rare cases occurred mostly when an intravenous bisphosphonate medication was administered to a patient who had a metastatic tumor, was receiving chemotherapy, and recently had major dental work.

**Bisphosphonates and Subtrochanteric Fracture**

Subtrochanteric fracture is a rare complication in patients who are receiving long-term bisphosphonate treatment. The preliminary study suggests that this fracture pattern is more common in the younger and more active patients who are taking bisphosphonates. Often these patients have prodromal pain in the affected hip prior to the fracture. It is hypothesized that the lack of remodeling in the subtrochanteric region of the femur in this young and active group of patients can lead to the insufficiency fracture.

**Parathyroid Hormone and Bone Tumors**

In laboratory rats, osteosarcomas were found in rats that received high doses of parathyroid hormone. So far, there have been no reported cases of the development of osteosarcomas in humans who are receiving parathyroid hormone therapy.

**Lifestyle Changes**

**Cessation of Smoking**

Smoking increases the chance of sustaining a fragility fracture. All individuals who smoke should be counseled on smoking cessation.

**Exercise**

Exercise can increase a patient’s balance and strength and decrease the chance of sustaining a fragility fracture.
Fall Reduction Program
A fall reduction program offers individualized treatment with a concentration on specific areas, including improved strength, improved balance, proper use of a cane or walker, proper eyewear and cataract evaluation, proper footwear, and home safety.

Calculating Fracture Risk

Dual X-Ray Absorptiometry Scan and Bone Density

T-score

The World Health Organization has defined the T-score in terms of how many standard deviations the patient’s bone mineral density is above or below the expected peak bone density for an average thirty-year-old of the same sex and race.\(^3\)

Z-score

The Z-score is defined in terms of how many standard deviations the patient’s bone mineral density is above or below the expected bone mineral density for someone of the same age, sex, and race.\(^4\)

For every reduction in bone density by one standard deviation, the fracture risk is doubled. The World Health Organization defines osteoporosis as a bone density that is more than 2.5 standard deviations below peak bone mass.\(^5\)

Limitation of Dual X-Ray Absorptiometry Scans
Two important risk factors for fractures are independent of bone mineral density measurements. These factors are age and the history of a previous fracture. With aging, fracture risk rises; therefore, for any given bone-mass measurement in absolute terms, an older person will have a greater risk of sustaining a fracture. A prior fragility fracture can drastically increase a patient’s risk of sustaining additional fragility fractures. Other important risk factors, such as smoking and secondary causes of osteoporosis, also increase a patient’s risk of sustaining a fracture in the future.\(^6\)

FRAX Risk Assessment Tool
Knowing a patient’s risk factors helps in the design of a more individualized strategy for osteoporosis management and fracture prevention. The World Health Organization has developed a fracture-risk-assessment calculator known as FRAX to address the previous limitations of measuring fracture risk.\(^7,8\) This is a comprehensive tool for calculating the ten-year absolute risk of fractures.

The clinical risk factors included in the model are age, sex, fracture history, bone mineral density of the femoral neck,
body mass index, a past prolonged use of systemic supra-physiologic glucocorticoid medication, history of rheumatoid arthritis, parental history of hip fracture, current cigarette smoking, and current alcohol intake. The decision to treat is made on the basis of whether a person’s absolute fracture risk meets a predetermined intervention threshold. These thresholds may be determined by various methods, including cost-effectiveness analyses. Currently, the thresholds for treatment in the United States are a ten-year absolute hip fracture risk of 3% and a ten-year absolute fracture risk of 20% for other fragility fractures. These thresholds may change as the cost of treatment continues to decrease.

The World Health Organization fracture risk assessment calculator, FRAX, is now available online (http://www.shef.ac.uk/FRAX).

Knowledge That What the Orthopaedic Surgeon Does Improves Bone Health

The literature has shown that orthopaedic surgeons have not done enough to aggressively diagnose and treat osteoporosis. It is important for orthopaedic surgeons to know that an aggressive osteoporosis disease-management program can decrease the rate of osteoporosis-related hip fractures by 25% to 50%. One such program is described below.

Background of the Kaiser Southern California Healthy Bones Program

Kaiser Southern California (Kaiser SCAL) is a health-maintenance organization in Southern California that is made up of eleven medical centers with 3.2 million members. Kaiser SCAL has an electronic medical records system that is capable of tracking dual x-ray absorptiometry scans, fragility fractures, and the medications used to treat or prevent osteoporosis. Kaiser SCAL has a fully integrated Healthy Bones Program in place at all eleven of its medical centers. The Healthy Bones Program was established by having orthopaedic surgeons serve as champions in a large multidisciplinary team comprised of healthcare providers from the following disciplines: endocrinology, family practice, internal medicine, rheumatology, gynecology, physical therapy, disease management and/or care management, radiology, and nursing education.

Materials and Methods

A prospective observational study was conducted to evaluate the effectiveness of the Healthy Bones Program on the management of osteoporotic disease in 650,000 patients in Kaiser SCAL from 2002 to 2007 inclusively. An electronic medical record system was used to collect data on these patients, including data on anti-osteoporosis medication usage, dual x-ray absorptiometry scans, and fragility fractures. For the study, we classified bisphosphonates, selective estrogen-receptor modulators, calcitonin, and parathyroid hormone as anti-osteoporosis medications. We did not include hormonal therapy, calcium, and vitamin D as anti-osteoporosis medications in our analysis, although they are helpful in the management of osteoporosis.

Source of Funding

No external funding source was used to develop or run the Healthy Bones program.

Results

Since the SCAL Healthy Bones Program was adopted, we have seen our annual dual x-ray absorptiometry scan utilization rate rise from 21,557 per year in 2002 to 78,262 per year in 2007, a 263% increase (Fig. 1). The annual dual x-ray absorptiometry scan utilization rate in men was 1549 in 2002, and it increased to 15,700 per year by 2007, a 914% increase. The annual number of patients receiving anti-osteoporosis medications rose from 33,208 per year in 2002 to 84,155 per year in 2007, a 153% increase (Fig. 2). The annual number of men who received anti-osteoporosis medications in 2002 was 2663, and that number increased to 9310 a year by 2007, a 250% increase. There was a large variation in the reduction...
in hip fracture rates at the eleven SCAL medical centers during the study period (Figs. 3 and 4). The reduction in hip fracture rate varied from 31.0% to 54.3%. The overall hip fracture rate reduction was 38.1%. That translated into preventing 970 hip fractures in calendar year 2007 (2544 hip fractures were predicted and the actual number was 1574) (Figs. 4 and 5).

Discussion

The most important thing an orthopaedic surgeon should know about prevention of osteoporotic fractures is that we can take action that helps to prevent hip and other fragility fractures. The first step is to consider that a patient may be at risk for the development of an osteoporosis-related fragility fracture. Simple steps, such as suggesting calcium and vitamin-D supplements for all patients and recommending bone mineral density testing for patients whose risk of the development of osteoporosis is high, should be considered as part of a surgeon’s daily practice.

An understanding of the pathophysiology of osteoporosis and fragility fractures will help in the development of a treatment strategy for patients. The medical management of osteoporosis is complex and can be accomplished by most practicing orthopaedic surgeons. For surgeons who do not wish to treat, it is still very important that they refer their patients who are at high risk for the development of osteoporosis or fragility fractures to either a primary care physician or an endocrinologist.

By aggressively identifying and managing patients who had osteoporosis, we were able to show a 38.1% reduction in the hip fracture rate in the Kaiser SCAL system. That translated to the prevention of 970 hip fractures in the year 2007 among our 3.2 million members.

The exponential increase in the hip fracture rate as our patients grew older was consistent with the findings of previous studies. As patients age, there is progressive deterioration of bone quality and an increased risk of sustaining a fall. The Healthy Bones Program aggressively targets older patients because these patients have the highest risk of sustaining a hip fracture. Other disease-management programs also have demonstrated that cost savings are greatest when the older age group is targeted.

We believe that it is possible to achieve at least a 25% reduction in the hip fracture rate in the United States by more aggressively managing patients who are at risk for osteoporosis. The first step toward this goal must be a more active role with regard to osteoporosis disease management on the part of orthopaedic surgeons.

The following recommendations are based on the ten steps outlined by the American Orthopaedic Association’s Own the Bone initiative.

1. Be a Champion—We Own the Bone!

Remember that addressing the problem of fragility fractures is multifaceted and will require a multidisciplinary solution. Identify potential partners in your community.

2. Set a Realistic Goal—Identify High-Risk Patients

Osteoporosis and fractures should not be considered a natural part of aging. A fragility fracture is defined as a fracture resulting from a fall from a standing height or less. The best predictor of a fragility fracture is a previous fragility fracture. The orthopaedic surgeon should focus on fragility fractures in men and women older than fifty years of age.

3. Be Proactive

Get into the habit of ordering dual x-ray absorptiometry scans and initiating anti-osteoporosis treatment for high-risk patients. Do not wait for someone else to do the right thing. Refer complex patients to endocrinology and/or internal medicine as needed. Patients at risk for falls should be referred for fall-reduction classes.

4. Teach Your Patients About Osteoporosis and Falls

Offer patient-education materials on osteoporosis and fall reduction. Do not try to create your own materials. There are plenty of free educational materials on the Web (see Appendix). Visit http://www.osteo.org to download materials that you can use, such as “Once is Enough: A Guide to Preventing Future Fractures.”

5. Do Not Wait Until Your Patient Has a Fragility Fracture

Develop an outreach program to prevent fractures by following the National Osteoporosis Clinical Practice Guidelines (http://www.nof.org/professionals/Clinicians_Guide.htm). Perform a dual x-ray absorptiometry scan for all women over the age of sixty-five years and all men over the age of seventy years. Perform a dual x-ray absorptiometry scan for men and women over the age of fifty years who have risk factors such as a previous fragility fracture, a family history of fractures, frailty, a low body mass index, or treatment with medications that increase the risk of osteoporosis.

6. Develop Preprinted Admission Sheets and Orders

Use a check-off sheet listing osteoporosis risk factors. Include orders for serum calcium, phosphate, and alkaline phosphatase; a complete blood-cell count (CBC); albumin; 25-hydroxyvitamin D; thyroid-stimulating hormone (TSH); parathyroid hormone (PTH intact); serum protein electrophoresis (SPEP); and kidney-function tests, including blood urea nitrogen (BUN), creatinine, and glomerular filtration rate (GFR).

7. Develop a Discharge Checklist for Patients with Fragility Fractures

Develop a discharge sheet that discusses osteoporosis and fall reduction. The discharge sheet should include: (1) a prescription for calcium (1200 mg daily), (2) a prescription for vitamin D (1000 IU daily), (3) a referral to physical medicine or physical therapy for fall-prevention education, (4) a recommendation for a home safety check, and (5) a referral back to the primary-care physician or a specialist for the evaluation of secondary causes of osteoporosis. When appropriate, order
dual x-ray absorptiometry scans and/or anti-osteoporosis medications.

8. Improve Your Discharge Documentation
Include the terms "fragility fracture" and “osteoporosis” in the discharge summary, and be sure that your letter to the patient’s primary-care physician points out your concern about the risk of future fractures.

9. Measure What You Have Done
It is very important to track how well your program is doing in terms of osteoporosis disease management. It is even more important to compare your results with those of other programs. The Healthcare Effectiveness Data and Information Set (HEDIS) measures are now being used to track the performance of osteoporosis disease programs. The Centers for Medicare and Medicaid Services may soon implement “pay for performance” osteoporosis measures.

10. Look at the New Fracture Risk Assessment Tool (FRAX)
The World Health Organization now has a tool, called FRAX, to assess a patient’s ten-year absolute fracture risk. Anti-osteoporosis treatment can now be based on a patient’s ten-year absolute fracture risk instead of solely on a T-score derived from a dual x-ray absorptiometry scan.

Conclusions
There is still a widely held misconception among many orthopaedic surgeons that nothing can be done to prevent or treat osteoporosis. The results of our study should help to dispel that misconception. By aggressively identifying and managing patients who were at risk of sustaining an osteoporotic fracture, we were able to show a 38.1% reduction in the hip fracture rate at our health maintenance organization in Southern California. That translated to preventing 970 hip fractures in the year 2007. We believe that, with the wide adoption of similar healthy bones programs, it will be possible to decrease the hip fracture rate in the United States by 25% or more. It is now time for orthopaedic surgeons to take action to address the problem of osteoporosis.

References

Appendix
The following organizations offer information about bone health and the identification and treatment of osteoporosis:
- Own the Bone Program (http://www.ownthebone.org)
- Washington University Osteoporosis Web Page (http://courses.washington.edu/bonephys/)
- American Academy of Orthopaedic Surgeons (http://www.aaos.org)
- United States Department of Health and Human Services, Office of the Surgeon General (http://www.surgeongeneral.org)
- National Osteoporosis Foundation (http://www.noafs.org)
- National Institutes of Health: Osteoporosis and Related Bone Diseases National Resource Center (http://www.niams.nih.gov/Health_Info/Bone/default.asp)
- National Women’s Health Information Center (http://www.4women.gov)
- Centers for Disease Control and Prevention National Bone Health Campaign (http://www.cdc.gov)


