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and Women's Center, Inc.

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OSTEOPOROSIS 2014

I initially decided to prepare this handout because I noted a great deal of confusion among my patients regarding the value of treating osteoporosis. I was also concerned about misunderstanding regarding the risks vs. benefits of treatment. Additionally, I have included information about prevention of this condition. I have tried to explain why prevention and treatment are important for maintaining our health, well-being, and independence so that we are better able to enjoy the process of aging.

Treatment recommendations include lifestyle and medications.

RISKS OF OSTEOPOROSIS:

Osteoporosis is a condition in which bone strength is reduced. As a result of weak bones, there is an increase in the risk of fractures. The condition is most common among postmenopausal women. Osteoporosis is diagnosed by DXA bone density scanning and/or by history of fracture.

It is a condition that accounts for approximately 17 billion dollars in annual health care costs in the USA. Among Caucasian women, fractures due to osteoporosis occur more commonly than all cases of breast cancer, stroke, and heart attack combined.

Vertebral (spinal, back bone) fractures are the most common type of fracture caused by osteoporosis. Often, this fracture has no symptoms and is discovered as an incidental finding during an x-ray. However, sometimes they may result in sudden severe back pain. These fractures often occur during minor, every-day activities (bending, lifting, pushing, pulling, coughing, or sneezing). Over time, these fractures can cause you to lose height and have a hunched back.

Hip fracture is the second most common type of fracture caused by osteoporosis. Hip fractures are usually caused by falling. In an individual with a prior history of hip fracture, there is a 20% incidence of a subsequent hip fracture. Following one hip fracture, an average of 50% of elderly individuals do not recover their pre-injury capabilities. For instance, many women are no longer able to walk on their own following hip fracture. It is not uncommon to require long term nursing home care due to this condition. Overall, complications that result from falling are the fifth leading cause of death among adults over age 65.

Wrist fractures: usually occur while falling with an outstretched hand. Complications of wrist fracture include pain, temporary disability (such as difficulty dressing, toileting, preparing meals), arthritis, chronic pain syndrome. Six months after wrist fracture, 23% of patients continue to report poor recovery of use of the hand.

LIFESTYLE:

Assure adequate CALCIUM and VITAMIN D intake. This will help to REDUCE THE RATE OF BONE LOSS, but likely increases bone density only minimally. It is important to distinguish between calcium that is consumed as part of a healthy diet compared with calcium supplements. The safest way to obtain your calcium is through diet. The best dietary sources of calcium are dairy products, especially milk. If you eat foods that provide you with 1,000-1,200 mg/day of calcium, you do not need to add any calcium supplement. There is a good resource listing calcium content of foods at the website for the National Osteoporosis Foundation: NOF.org.

For women whose diet does not contain calcium, supplements are advised. This should consist of 1200mg/day of elemental calcium.

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Recent studies have questioned the cardiovascular safety of calcium. I think that it is important to point out that there is NO increase in mortality from all causes among women taking dietary calcium or calcium supplements. In fact, in the Women's Health Initiative study, among a large number (36,282) of women between ages 50-69, there was NO EFFECT on CARDIOVASCULAR DISEASE among women taking calcium supplements containing 1,000mg calcium + 600 IU Vitamin D daily. Other recent analyses of the relationship between calcium and cardiovascular disease may indicate an adverse effect among men but not among women. Additionally, some studies that have indicated increase cardiac risk did not actually document the presence of heart disease.

Until we have more information, again note that it is safest to obtain your calcium through diet. Avoid large doses of calcium taken at one time (no more than 600mg of calcium should be taken at once). Do not exceed 2,000mg/day of calcium as part of your normal routine. Another concern about calcium supplements is their potential to cause kidney stone formation. By comparison, dietary calcium does not increase the risk of developing kidney stones. Adverse side effects of calcium include constipation and indigestion. . Vitamin D intake should be approximately 800 IU/day. Vitamin D3 is the D of choice as it is more efficient at increasing blood levels of Vitamin D (compared with Vitamin D2). The recommended dosage of Vitamin D3 is 800 IU/day. It is considered safe up to 4,000 IU/day, although toxic effects above this dosage have not been identified. Some data indicates that there may be a modest elevation in risk of pancreatic cancer when serum levels of Vitamin D exceed 40-50ng/mL. In addition, some data indicates that, among black women but not white women, fracture risk actually increases when the Vitamin D level in the blood is > 20ng/mL. When taken in combination, there is data indicating that calcium + Vitamin D reduce risk of fracture. However, the mechanism by which we see fracture risk reduction is not clear as the effect on bone density is not significant.

Exercise for 30 minutes three times each week is recommended. This has been shown to reduce risk of hip fracture and overall fractures. Exercise has been shown to increase bone density in both spine and hip. The BEST exercise is the one that you enjoy most. Walking and jogging are equally effective. Jumping is good for bone density. Resistance strength training is also excellent for reducing overall fracture risk. Balance training is helpful for prevention of falls. It is important to continue with a regular exercise program because, once you stop, the benefit is gone.

Other important lifestyle factors to help prevent fracture include prevention of falls: make sure that you can see and hear as well as possible. Be cognizant of the effect of bifocals, trifocals, progressive lenses especially when walking down stairs. (When you look down the steps, if you are viewing through your reading lenses, the brain will perceive the step to be closer than is really the case, potentially throwing you off balance and causing a fall). Do not dress or undress on hard tile bathroom floors in the bathroom – a most unforgiving place to fall. Dress and undress from seated position rather than while standing and balancing on one leg. Be sure to use grab bars when appropriate. Do not keep clutter, electric wires or other items on the floor. Avoid throw rugs in your home. Tack down area rugs. When away from home, be especially careful. Do not walk and go sight-seeing at the same time (this is how I fell off a curb and how one of my patients fractured her hip).

If you are a cigarette smoker, stop. Smoking increases the rate of bone loss. Avoid heavy consumption of alcohol as this can both reduce formation of new bone cells and increase breakdown of old bone cells. Alcohol increases the hormone cortisol, having an adverse effect on bone density (similar to prolonged Prednisone treatment). Additionally, heavy alcohol intake (more than two drinks/day) also increases the risk of falling.

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MEDICATIONS:

HORMONE REPLACEMENT THERAPY: is FDA approved for prevention but not for treatment of postmenopausal osteoporosis. While on estrogen, there is good preservation of bone strength and prevention of fractures. There is a reduction in both vertebral (spine) and hip fracture of over 30%. However, a year after discontinuation, bone density will decline to the same level that it would have been had you not previously been on hormone replacement therapy.

BISPHOSPHONATES: (e.g. Fosamax, Actonel, Atelvia, Boniva, Reclast).

This class of medication is the first line treatment for osteoporosis and for increased fracture risk. They are also used to prevent osteoporosis. Bisphosphonates reduce risk of fracture by 50% and reduces mortality by 30%. They work by slowing the breakdown (resorption) of bone that occurs naturally after menopause.

Fosamax (alendronate) and Actonel (risedronate): These oral medications are available in daily, weekly, and monthly formulations. They should be taken first thing in the morning on an empty stomach with 8oz of water (distilled water is best as it has no minerals or impurities that could reduce absorption of the medication). Then wait 30 minutes prior to eating or taking other medication. Do not lie down for 30 minutes after taking the medication. Atelvia (enteric coated risedronate) is taken after breakfast with four oz of water. These medications reduce risk of both vertebral fractures and hip fractures. Fosamax has data that bone density may be maintained for several years after the medication has been discontinued. (Thus some women may be candidates to take a "drug vacation" after several years use. However, there the medication will continue to improve bone strength when used for up to ten years).

Boniva (ibandronate): is available in both oral and intravenous formulations. The oral formulations include daily and monthly dosing while the intravenous (IV) is given every three months. It reduces the risk of vertebral (spine, back) fractures but has not been demonstrated to reduce risk of hip fracture.

Side effects of oral bisphosphonates are usually mild, with the most common being GERD (reflux, heartburn). The medications cannot be used in women with severe kidney disease.

Bisphosphonate data has also indicated additional health benefits including reduction in risk of breast cancer, colon/rectal cancer, gastric cancer, and stroke.

Reclast (zoledronic acid): This is a once a year intravenous medication. The medication is infused over 15 minutes. Side effects include fever, flu-like symptoms, headache and muscle and joint aches, especially the first time you are treated. The side effects are lessened by taking Tylenol or ibuprofen prior to the infusion. There has been a lot of media attention to potential serious complications of bisphosphonate therapy. The first reported serious side effect was osteonecrosis of the jaw (ONJ). This is a condition in which there is formation of tiny holes in the jaw bone. The risk of ONJ is significantly increased among cancer patients receiving high dose (higher dose than what is used to treat postmenopausal osteoporosis) intravenous (IV) bisphosphonate medication. These are patients with cancer that has metastasized to bone. The incidence of ONJ in this group of patients is 1-10/100 patients. By comparison, among patients not being treated with this medication for cancer, the incidence of ONJ is 1 patient in 7,700 with IV bisphosphonate and 1/10,000-1/100,000 with oral bisphosphonate.

The other serious adverse effect report from bisphosphonate medications is that of atypical femur fracture – spontaneous break in thigh bone in the absence of any injury to the bone. Overall, the incidence of this type of fracture is less than 1/100,000. For women receiving IV zoledronic acid (Reclast), the incidence after 7 years of continuous use was 1/500.

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After five years of bisphosphonate use among 1,000 women, 50-115 vertebral fractures are prevented. 35-50 other fractures are prevented (hip, wrist, shoulder). 5 atypical femur fractures occur.

SELECTIVE ESTROGEN RECEPTOR MODULATORS (Evista/raloxifene, tamoxifen). These medications are particularly helpful in increasing bone density in the spine. They are also used to reduce risk of breast cancer. Side effects include hot flashes. Risks include blood clots. (We may see data on Ospheña/ospemifene in the future).

ANTIBODY: (Prolia/denosumab): This medication is an antibody that prevents breakdown of bone cells. It improves bone density and reduces fractures at all sites (vertebra and hip). It is administered by subcutaneous injection every 6 months. It is usually well tolerated. Potential adverse reactions include skin infection and dry skin. It can temporarily lower blood calcium level, but this usually does not occur in women with normal kidney function and in those who have adequate calcium and Vitamin D intake.

CALCITONIN: This is a hormone produced by the thyroid gland and helps to regulate calcium metabolism. It is administered as a nasal spray or subcutaneous injection. It helps to increase bone density in the spine, but may be less effective than other alternative medications. It has been used for its pain relieving effect during acute vertebral fracture.

PARATHYROID HORMONE/PTH (Forteo): This is a hormone produced by the parathyroid glands. When administered by daily injection, it stimulates bone formation in the spine. It is very expensive. It is used for severe osteoporosis for patients with history of both osteoporosis and prior fracture. The medication is used for up to two years duration. After discontinuation, bone loss will resume, so it must be followed with another medication. Data has shown this hormone to be associated with osteosarcoma (a type of bone cancer) in rats, but there has never been a case report of this condition in humans.

CONCLUSION:

Menopause is a time of rapid aging. For our bones, this means that old bone cells are broken down at a faster rate than new bone cells are forming. Thus we have a net loss of bone, resulting in weakening of bones and increased risk for fracture. Fractures in the back occur at an earlier age than fractures of the hip. The vertebral bones are small and lose bone density 10-20 years before we generally start to experience loss of bone density in our larger, heavier hip bones. Vertebral fractures are often silent (although rarely do cause severe pain). They can result in a hunched back. Multiple vertebral fractures will alter the shape of our abdomen and chest. Over time, this can result in intestinal symptoms and breathing difficulties. Wrist fractures can limit our ability to carry out normal activities of daily living such as dressing or washing our hair. Hip fractures are associated with the greatest morbidity and mortality of any of the osteoporotic fractures.

We can have a positive impact on the aging process. There is much that we can do to maintain bone density, including diet, Calcium, Vitamin D, exercise, prevention of falls, avoiding known risks such as smoking or excess alcohol intake. If we are diagnosed with osteoporosis or increased risk for fracture, there are numerous medications that reduce fracture risk and reduce morbidity and mortality. For most of us, there is a medication formulation that is safe, effective and well-tolerated. Serious adverse side effects are rare. The goal of treatment is to prevent fractures, thereby preserving our independence and quality of life.

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3/4/2014

Dr. Shuster is certified by the International Society for Clinical Densitometry as a Certified Clinical Densitometrist and Certified Clinical Bone Densitometry Technologist.