

THE NATIONAL WOMEN'S HEALTH NETWORK

Osteoporosis

FACT SHEET



Osteoporosis is a disease, more common in women, that causes bones to become fragile and more susceptible to breaking. Fractures and the consequent pain and disability can seriously affect women's health and their quality of life. Some women -- most commonly those who don't have good access to health care -- experience fractures that could have been prevented if their osteoporosis had been treated. At the same time, not every woman who is warned about bone thinning needs to be worried. Companies that make drugs for osteoporosis have conducted advertising campaigns for women and health care providers that have created fear and led many women who don't need the drugs to take them, despite serious side effects and risks. In recent years, many new osteoporosis drugs have become available, creating a dilemma for women trying to decide which, if any, of these medications they need. Specifically, women want to know when it is appropriate to take a drug for osteoporosis, and which treatments are safest and most effective. The NWHN believes that efforts should be focused on promoting bone health by preventing fractures rather than preventing loss of bone mineral density in women who are otherwise at low risk of experiencing a fracture. As you'll read below, drugs are not always the best approach. We've developed this fact sheet to help women un-

derstand several aspects of osteoporosis -- what it is, screening tests are available, prevention and treatment with prescription drugs, and alternative approaches to prevention. It can help women make informed decisions about if they need drug treatment at all and if needed which drugs are most effective and have the least side effects.

Osteoporosis literally means porous bone. Throughout life, there are constant changes in the structure of bones. A natural process breaks down bones and builds them back up again at the microscopic level. Children and young adults build more bone than they break down. Pregnant women release bone to transfer needed minerals to the developing fetus and then build up their own bone strength again after giving birth. After age 35-40 all adults begin to lose bone as the breaking down process increases and the building process decreases. For a few years around the time of menopause, women lose bone more quickly, possibly because they no longer need extra stores of minerals to support a developing fetus. Osteoporosis occurs when bones become weak and fragile. Osteoporosis has several causes -- age alone is a risk factor for osteoporosis, especially in people who didn't build up their bones to their fullest potential as a child and young adult medication can cause osteoporosis -- taking high

doses of steroids for months or years causes significant bone loss, for example. Removing women's ovaries increases their risk of getting osteoporosis. Inactivity can cause osteoporosis, too — astronauts and people who are not able to walk briskly are more likely to develop fragile bones. People who have osteoporosis are at greater risk for fracturing their bones, especially in the hip, vertebrae (spine) and wrist. Hip fractures lead to hospitalization, often are surgically treated, and can take a long time to heal. Many women never fully recover after a hip fracture. An acute vertebral fracture of one or more vertebra is usually very painful. However, these fractures can be painless and are sometimes not diagnosed until long after they occur and are seen on X-rays done for other reasons. For example, thoracic vertebral fractures can easily be seen on a chest X-ray.

OSTEOPOROSIS SCREENING

In the 1980s, women's health advocates were concerned that the medical community had overlooked the effect of bone fractures on older women's quality of life. We advocated for change — but today the pendulum has swung to the other extreme. For more than a decade, big drug companies have used promotional campaigns to convince health care providers and women that osteoporosis not only affects older women, but also those at middle-age. Despite the fact that independent medical experts recommend women not be screened for osteoporosis until age 65 unless they have an unusual risk factor like long-term steroid use, osteoporosis screening is now widely promoted for women in their 50s and even 40s by physicians, drug companies and companies that make bone mineral density equipment. The most common screening tool is a DEXA X-ray scan, which measures bone mineral density in the hip spine or elsewhere. DEXA results compare a woman's bone density to that of a healthy young woman (almost guaranteeing the scan will reveal bone loss, since everyone loses bone with age). If a woman's bone density is significantly lower than a young adult's, she is diagnosed with osteoporosis. Some clinicians are now warn-

ing women with bone density that is only slightly lower than the young adult average that they have "osteopenia" — a term that describes reduced bone density, but is neither a disease nor disorder. DEXA machines are safe and pose no health risks, but the push to use them earlier and diagnose osteopenia can lead to early, unnecessary and possibly dangerous treatment. As a result, women end up taking expensive drugs for decades that may have serious risks and/or side effects. Moreover, while the scan can predict fracture risk in the short-term, it cannot accurately predict the risk of fractures occurring decades in the future; thus, a scan taken at age 45 generally has no value for predicting what may occur when the woman is 70 (when debilitating fractures are most likely to occur). The accuracy of DEXA machines may not be as good in real life as it has been shown to be in carefully controlled research settings. Specialists have observed that very small changes in positioning of the hip and spine for BMD studies result in large differences in T scores. There is also a lot of variation between machines even from the same manufacturer. These differences caused by error may be as much as any change in bone density that a woman is actually experiencing. We recommend that women getting repeat scans have them done on the same machine, if possible. A recent study found that the majority of older women who are scanned starting at age 65 are found to have low risk for serious fractures and can safely wait five or ten years before getting another scan.¹ Questions also exist about the value of such screening for women of color. The original DEXA studies did not include any women of color, so there's a lack of good information about normal bone density scores, and what score might indicate concern about the risk of bone fractures, for these populations. African American women typically have denser bones and lower fracture rates than White women, while Asian American women typically have thinner bones, but also have lower fracture rates than White women. NWHN believes that research is needed on both osteoporosis and the use of DEXA scans in women of color, and until such research has



been conducted we recommend that women of color approach screening with even more caution.

DRUG TREATMENTS

Women diagnosed with osteoporosis or osteopenia are usually told they need to take prescription medication to prevent further bone loss and reduce the risk of fractures. The most common drugs are:

HORMONES

The Food and Drug Administration (FDA) has approved estrogen and progestin treatment to prevent osteoporosis — but not to treat it. Both estrogen alone and combinations of estrogen and progestin reduce women's risk of osteoporosis and bone fracture. But, the hormones also increase the risk of breast cancer, heart attack, stroke, and pulmonary embolism. So, these hormones should be the last choice for osteoporosis prevention and should be used only when other prevention methods are not safe or appropriate for a particular woman. Two other hormones have been approved to treat osteoporosis: teriparatide and calcitonin. Teriparatide (brand name: Forteo) is a derivative of human parathyroid hormone (PTH), the primary regulator of calcium and phosphate metabolism in bones; a daily 20 mg injection has been shown to stimulate new bone formation and prevent spine, hip, wrist and other bone fractures in women with osteoporosis. Teriparatide is generally used only for women with severe osteoporosis, because most people don't want to get shots every day and side effects can include nausea, leg cramps, and dangerously high calcium levels. It's also very expensive, and some insurance companies are reluctant to cover it. Calcitonin (brand names: Fortical or Miacalcin; not the same as calcium supplements) has been shown to prevent fractures of the spine but not of the hip and wrist. It is approved to treat women with osteoporosis, but its approval was based on weaker evidence than more recently approved drugs, and its use is not generally recommended. Women who take calcitonin must watch their intake of foods with high calcium levels (e.g. milk, cheese) as excessive calcium can be dangerous. Calcitonin is administered through a nasal spray; side

effects may include nasal congestion and nausea.

BISPHOSPHONATES

Bisphosphonates are widely prescribed for osteoporosis treatment and prevention. The FDA has approved eight bisphosphonates to prevent bone loss and fractures in post-menopausal women: alendronate (Fosamax), etidronate (Didronel), ibandronate (Boniva), risedronate (Actonel), tiludronate (Skelid), pamidronate (Aredia) and zoledronic acid (Reclast and Zometa).² Some are taken daily; others are formulated for weekly, monthly or yearly use. Bisphosphonates decrease bone absorption and slow down bone loss. The drugs are also incorporated into newly formed bone and can persist in them for years, so the effects last well beyond cessation of use. In May 2012, in an important update, the FDA expressed concerns about the safety and effectiveness of bisphosphonate use beyond 3 to 5 years. The agency told manufacturers that women must be made aware that long-term use may not be helpful. This advice, based on an analysis of recently published long-term follow-up studies of women taking bisphosphonates, challenges the "screen early, treat indefinitely" approach promoted by drug company marketing. According to these studies^{3,4,5}, women who received continuous bisphosphonate treatment for 6 or more years had a fracture rate between 9.3% and 10.6%, while patients who did not continue the treatment after 3-5 years actually had a lower fracture rate of between 8.0 and 8.8%. In light of these studies, the FDA states that they believe that women at low risk of fracture should consider stopping bisphosphonates after 3-5 years. NWHN believes that it is also very important for women to carefully consider whether or not to start these drugs in the first place. We have asked the FDA to re-consider the use of these drugs for prevention, based on our concern that many women are experiencing complications from these drugs with little to no chance of benefit. In addition to questions of efficacy, there are safety concerns. Bisphosphonates seem to have fewer risks than hormones, at least in the first five years, but these drugs have several health problems as-

sociated with them. There have been numerous reports of unusual fractures of the bone that take longer to heal. Some women may experience severe bone, joint, and/or muscle pain after starting a bisphosphonate. The FDA advises patients with such pain to consider discontinuing the drug, which usually causes the pain to go away. The jaw tissue of some women taking bisphosphonates dies (jaw necrosis), which can necessitate removal of an area of the jaw bone. Bisphosphonates also can cause severe heartburn and ulcers and damage the stomach and esophagus if not taken in a very careful regimen (on an empty stomach, with a full glass of water, while sitting upright for up to an hour). In July 2011, the FDA announced that it was conducting a safety review of bisphosphonates in the light of concerns about an increase in risk of esophageal cancer.⁶ The Network is closely following this subject to provide timely information that may protect women from any potential health hazards of indiscriminate bisphosphonate use.

SELECTIVE ESTROGEN RECEPTOR MODULATORS (SERMS)

SERMS are compounds that act like estrogen on some tissues (eg. bone tissue) and have an anti-estrogen effect on other tissues (eg. breast and sometimes uterus). The FDA has approved raloxifene (Evista) to prevent and treat osteoporosis. The drug has been tested more extensively than bisphosphonates and although it reduces the risk of spine fractures, it does not reduce hip fracture risk. It also raises different safety concerns that include increased risks of blood clots, hot flashes, nausea, and leg cramps. In September 2008, the FDA held an advisory committee meeting to discuss an application to approve another SERM, lasofoxifene, for the treatment of osteoporosis in postmenopausal women. Research reviewed by the FDA showed that lasofoxifene appears to reduce spine fractures in the first three years of use. Like raloxifene, it increases the likelihood of blood clots, and it also increases vaginal bleeding and women taking the drug were subjected to more invasive procedures such as endometrial biopsies, D&Cs and even hysterectomy. The NWHN recom-

mended to the FDA that approval of lasofoxifene be delayed until the agency can fully review the research on extended use so that we'll know more about the effects and effectiveness of using the drug for extended periods of time. NWHN also expressed concern that Pfizer, the company that makes lasofoxifene, will encourage women to take this drug for other uses that haven't been fully evaluated by the FDA. Subject to FDA's request for more information, in 2010 Pfizer decided to withdraw its application for approval of lasofoxifene. This year (2012) Pfizer is seeking approval for a new hormone therapy (Aprela), with claims of delivering benefits of HT without the risks by combining estrogen with bazedoxifene. Bazedoxifene, a similar SERM to lasofoxifene is approved for treatment of osteoporosis in Europe, but not in the USA due to FDA's concerns about its side effects of strokes and blood clots.⁷ NWHN will monitor the FDA approval process for this proposed new drug very carefully and will report our findings as soon as possible.

MONOCLONAL ANTIBODIES

A new class of medication (denosumab) is a monoclonal antibody that inactivates the natural bone breakdown mechanism. In 2010, the FDA approved denosumab for osteoporosis treatment. Sold as Prolia, it is an injection given twice a year for osteoporotic patients in whom other treatments have failed or who have severe osteoporosis and a high risk for fractures. While the drug has been shown to be effective in reducing fractures and preventing bone loss, it also causes significant health problems. Denosumab's cellular target in bone also exists in the immune system and serious infections requiring hospitalization (eg. heart infections), skin reactions, atypical fractures and slow healing of fractures are among the side effects. Concerns exist that its immune system effects could include ovarian and cervical cancer, pancreatic cancer and breast cancer recurrences. Prolia is an expensive medication with uncertain effects of long term use. The original trials were conducted in women who were 72 years old on average.⁸ The NWHN is concerned that for most postmenopausal women the benefit of Prolia does not outweigh the risks.

We recommend that women requiring osteoporosis treatment not try denosumab until they've tried other FDA-approved osteoporosis medications.

ALTERNATIVES

Alternatives to drugs exist for making and keeping bones strong. The National Institutes of Health's 2000 Consensus Statement on Osteoporosis reviewed the research on osteoporosis prevention and treatment and found strong scientific evidence that calcium and Vitamin D intake are crucial to develop and preserve strong bones.

Regular exercise (especially resistance and high-impact activities) contributes to the development of bone mass. Other promising interventions focus on preventing fractures: balance training reduces the risk of falling, which is often responsible for broken bones in older people. A few small studies have shown that hip protectors, along with training on how to use them can help reduce the risk of fracture if a fall occurs. Large randomized trials didn't find any benefits, though. Other practical ways to reduce the risk of falling include making sure that vision prescriptions are up-to-date, checking prescriptions for drug interactions that might cause dizziness, eliminating fall-causing hazards in the home (like slippery rugs, grandkids' toys with wheels), and wearing appropriate shoes.

THE BOTTOM LINE

Drug companies are clearly trying to expand the market for osteoporosis drugs; their latest efforts target "non-traditional" populations (like younger women and men) for screening. The NWHN encourages women under age 65 to reject bone density screening unless they have unusual circumstances that increase their risk. In addition to thinking carefully about their own risk of experiencing a serious fracture, women need to consider safety issues when deciding whether to take osteoporosis drugs. Also, the treatment's duration is critical in determining its effectiveness: when a woman stops taking certain osteoporosis prevention drugs, the preventive effects are quickly lost. Don't hesitate to ask your health care provider about the safety and efficacy of osteoporosis med-

ications and whether non-drug alternatives might be just as effective, based on your personal history and current health status. For more information visit the National Institutes of Health Osteoporosis and Related Bone Diseases Resource Center's website.

CONTACT US

The National Women's Health Network is committed to ensuring that women have access to accurate, balanced information. For more information, email us at healthquestions@nwhn.org or call the Women's Health Voice at (202) 682-2646. Stay informed, connect with us on Facebook and Twitter.

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