PharmaNotes

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Medications Used to Treat Osteoporosis

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Osteoporosis is a disease of the bones that causes decreased bone mass. With time, bones become more fragile and break more easily resulting in fractures. Decreased bone mass typically is caused by a shortage of calcium and vitamin D in the body. If the body does not get enough calcium and vitamin D that it needs through the diet, it releases calcium and vitamin D that has been stored in the bone. Our bodies constantly break down and rebuild bone as part of the natural process. However, decreased bone mass occurs if bone releases stored nutrients faster than the bone is rebuilt. Osteoporosis is known as a "silent disease" because many patients are unaware they have low bone mass until a fracture occurs.

Older adults need 1200 to 1500 mg of calcium a day through diet and supplements.

Calcium and vitamin D are essential to bone health. Most patients do not know how to correctly use these supplements. See "*How to Choose a Calcium Supplement*" on page.4.

Bone loss is detected by measuring bone mineral density (BMD). BMD is recorded as a T-score. Physicians use T-scores to diagnose osteoporosis and predict a patient's fracture risk. The score compares a patient's bone mass to normal average bone mass. Osteoporo-

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Medications in the News

In early January 2008, the cholesterol medication Vytorin® made the news because preliminary results from a study known as the "ENHANCE" trial were made public. Vytorin is a combination cholesterol-lowering drug that contains simvastatin (Zocor®) and ezetimibe (Zetia®). The study evaluated changes in carotid artery wall thickness in patients receiving the combination drug Vytorin versus just simvastatin. The results found that the combination drug was no more effective than simvastatin alone in decreasing thickness of the artery wall. As expected, the combination drug lowered cholesterol levels more than simvastatin. There was no difference in safety between the 2 study groups.

The news media raised the concern that Vytorin is not effective and its use should be limited. Unfortunately, the news media did not include all pertinent information, and many patients worried needlessly about their cholesterol medicines.

When alarming information like this hits the news and radio, the most appropriate response from health care professionals is that (a) patients should not panic, and (b) they should talk with their physician before making any changes to their medicines. Another

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Table. Who should have a bone density test?

- All women over 65 years old
- Post-menopausal women with risk factors
- Women who have had a fracture
- Men over 70 years old or with risk factors

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sis is defined as a T-score less than -2.5. A T-score greater than -1 is considered normal.

What is Osteopenia?

A T-score between -1 and -2.5 is called osteopenia. This is a condition of low bone mass, but milder than osteoporosis. It is considered one of the first steps towards osteoporosis and should be monitored by a physician. It may or may not need to be treated.

Who is at risk?

The most common risk factors for osteoporosis include increased age, post-menopausal changes, and certain medications and disease states. Other risk factors include inactive lifestyle, body weight less than 125 lbs., low lifetime calcium intake, and smoking. The table lists who should get a bone density test.

When is treatment needed?

Based on fracture risk and T-score, a physician might decide to start prescription therapy to treat osteoporosis. Several different medications are available that increase BMD and/or decrease fracture risk. This is very important because over 50% of women and 25% of men will have a fracture in their lifetime.

Even when taking one of these prescription medications, it is necessary to get 1200 to 1500 mg calcium each day and 600 to 800 units of vitamin D each day. Calcium is the major component of bones, while vitamin D helps improve calcium absorption and is needed for proper bone formation. Vitamin D also has been associated with reducing the risk of falls.

What medications are used to treat osteoporosis?

All of the treatment options listed below work by decreasing the breakdown of bone. Teriparatide (Forteo®) is unique in how it works because it actually stimulates new bone formation, rather than simply preventing the breakdown of existing bone.

1. *Bisphosphonates*: Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), Reclast® (zoledronic acid)

- Benefits: Reduce the risk of spinal and hip fractures and increase BMD at the spine and hip.
- Precautions and side effects: The most common side effects are nausea and heartburn.
- Important facts: These medications must be taken first thing in morning only with water, 30 minutes before food, and patients must remain upright for 30 minutes. These directions improve absorption of the drugs and decrease side effects. Boniva is taken just once a month; Reclast® is administered as an injection once a year. The bisphosphonates often are considered 1st choice agents. How long to continue a bisphosphonate is not fully

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Should We Use Antibacterial Soaps?

Washing your hands with antibacterial soap that contains the active ingredient *triclosan* is not more effective than using plain soap. A study found that washing hands with soap that contained triclosan compared with plain soap did not remove more bacteria from the hands. It also was no better in preventing infectious illness symptoms. Widespread use of triclosan raises the concern that some bacteria may become resistant to common antibiotics such as amoxicillin. However, no such resistance has been detected to date. The study did not evaluate alcohol-based sanitizers, like Purell® or GermX®, and these are not a concern.

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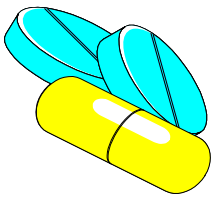
known, but recent information suggests that a cycle of taking a bisphosphonate for 5 years, then stopping for 5 years might be appropriate except for highest risk patients.

2. *Selective estrogen receptor modulators (SERMs):* Evista® (raloxifene)

- Benefits: Reduces risk for spinal fractures and increases BMD at the spine and hip
- Precautions and side effects: Most common side effect is hot flashes.
- Important facts: Evista® has been associated with an increased risk of blood clots and should not be used in women with a current blood clot or who have had one in the past.



3. Calcitonin nasal spray: Miacalcin®, Fortical®

- Benefits: Calcitonin may provide some pain relief for patients with recent vertebral fractures.
- Precautions and side effects: runny nose, nosebleeds, nasal irritation.
- Important facts: It is less effective than other agents in improving BMD and reducing fracture risk.

4. *Parathyroid hormone:* Forteo® (teriparatide)

- Benefits: Forteo® is the only medication available that actually stimulates new bone formation. It reduces risk of spinal and hip fractures; increases BMD of hip and spine more than the bisphosponates.
- Precautions and side effects: This drug should not be used in patients with Paget's disease or who have had skeletal bone radiation. The most common side effects are pain at the injection site and dizziness.
- Important facts: Forteo® is only available as a subcutaneous injection and must be refrigerated. Due to the high cost and concern for potential adverse events, Forteo® is reserved for patients who are unable to take bisphosphonates and who are at very high fracture risk.

5. *Hormone replacement therapy (estrogen with or without progestin):* Climara®, Estrace®, Premarin®, Vivelle® Activella™, FemHrt®, Premphase®, others

- Benefits: decreases risk of spinal and hip fractures; increases BMD at spine and hip.
- Precautions and side effects: Hormone therapy increases the risk of stroke, breast cancer, and blood clots. These therapies no longer are promoted for treating osteoporosis.
- Important facts: Women should discuss

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About HbL PharmaConsulting

HbL PharmaConsulting offers professional consultations to patients who take multiple medications. The goals of each consult include preventing and correcting medication-related problems, improving patient quality of life, and identifying ways to reduce drug costs. For more information, contact Dr. Levy.

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the risks of hormone replacement therapy with their physicians. Women with an intact uterus must use estrogen combined with a progestin to decrease the risk for endometrial cancer.

Can I prevent osteoporosis?

Prevention is key! By 20 years old an individual has acquired 98% of their total bone mass. By starting young and building strong bones during childhood, osteoporosis may be prevented later in life. For individuals greater than 65 years old, there are other lifestyle changes that can help decrease the risk for osteoporosis:

- Quit smoking
- Limit alcohol intake
- Increase physical activity, especially weight bearing and resistance exercises
- Get enough calcium and vitamin D each day.

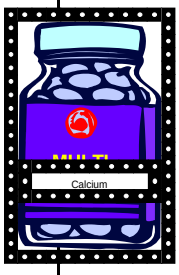
Summary

This article describes the several medicines that can be used to treat osteoporosis and the importance of getting enough calcium and vitamin D. Treatments have been found to be effective in clinical trials. In the real world, though, it sometimes is difficult for patients to continue therapy long term for several reasons. Challenges include medication side effects, lack of symptoms associated with osteoporosis, not knowing whether the treatment is helping, not taking calcium and vitamin D correctly, and not understanding the disease.

If you have been diagnosed with osteoporosis or have questions about your bone health, talk with your physician or pharmacist. For additional information on treatment options and supplements for treating osteoporosis, contact Dr. Levy at HbL PharmaConsulting.

How To Choose a Calcium Supplement

If you are not getting the required amount of calcium and vitamin D through the foods you eat, a nonprescription supplement may be necessary. There are many types of calcium products available with or without vitamin D. Different types of calcium are used in these products: calcium carbonate (as in Oscal® or Caltrate®) and calcium citrate (as in Citracal®) are the 2 most common types. The type of calcium you buy determines how you should take the supplement. Follow these important tips to use your calcium supplement correctly.



◊ If your product contains calcium **carbonate**, it needs to be taken **with meals** to ensure it is absorbed properly. Calcium **citrate** can be taken **with or without food**. Check the ingredient label to know what type of calcium you have.

◊ Spread out your calcium doses. The stomach can absorb only about 500 to 600 mg of calcium at one time, so you will need to separate the doses. Do not take more than 600 mg calcium at one time. For example, you might have to take one 500-mg tablet of calcium with breakfast and another tablet with lunch.

◊ Read the ingredient label to know how much *elemental calcium* is in each tablet or capsule. Calcium *citrate* products usually have about 200 mg per tablet, thus the dose would be **two** tablets.

◊ Buy a calcium product that contains vitamin D to ensure you get enough vitamin D.

◊ If you take a multivitamin, check to see how much calcium and vitamin D it contains.

◊ Talk with your pharmacist about drug interactions with calcium, and be sure to let your physician know if you are taking a supplement.

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recommendation all consumers should heed is to ask their pharmacist about the *real* story behind the news story. Many times, research results apply only to a specific patient population or medical situation.

The ENHANCE trial evaluated patients with a very specific, less common type of high cholesterol. Their cholesterol levels were much higher than what we usually see in patients being treated for high cholesterol. In addition, the main outcome of the study was change in thickness of the carotid artery wall. This outcome is considered a *marker* for stroke risk, but it may or may not translate into increased strokes or heart attacks. In contrast, a more important outcome when treating high cholesterol levels is how often strokes or heart attacks occur in patients taking a medication to lower cholesterol.

In response to the news hype, two national heart organizations stressed that further study and evaluation is needed. There is no reason to be concerned about the safety or effectiveness of Vytorin at this time. The results of the study are prelminary; details and data from the study are not yet available for review; and it has not yet been published in a medical journal. These steps allow the study to be critically reviewed by experts and help catch potential errors or pitfalls of a study.

Thus, be careful of what you hear in the news or on the radio. The story talking about the latest drug research likely does not tell the complete story. — HbL