Osteoporosis medications: Are they worth the risk?

At our center we encounter questions regarding the side effects of osteoporosis medications on a daily basis. We hear your concerns and would like to comment on our experiences in conducting research utilizing many of the available medications as well as prescribing them in our patient practice. In addition, we would like to revisit some important facts regarding osteoporosis and fractures.

Let us reflect that just 20 years ago we did not have any effective drugs to aid in the prevention of osteoporosis and resultant fractures that resulted from such low trauma.

As the National Osteoporosis Foundation (NOF) describes, osteoporosis occurs when bone, which is constantly being replenished, breaks down faster than it gets replaced, leaving the skeleton porous and brittle.

Medications new and old

Just like with any medications, the first ones out may not be the best ones, but we do not always know that at the time. This is why our research unit exists, because we have to continue to study the effects of new medications and look at the effects of older medications taken on a long-term basis. Over the past 20 years, many individuals have taken these medications and have had successful outcomes.

An analysis published earlier this year in the New England Journal of Medicine estimated that for every 1,000 women with osteoporosis treated up to five years, bisphosphonates prevented 100 fractures and caused at most, only one.

We need to remember why we take these medications: It’s not to see a huge jump in our bone mineral density (BMD) or to cure our osteoporosis, it’s to manage it by preventing FRACTURES!

The fracture phenomenon

Fractures, writes the NOF, are “deadly for older Americans.” At least one-fifth of older women—and a higher percentage of older men—who sustain a hip fracture die inside of a year. Additionally, the foundation reports, one in five hip fracture survivors lands in an assisted-care facility, “losing precious independence.”

In an article published recently in The Wall Street Journal, Melinda Beck writes: “Each year in the U.S., osteoporosis causes some 700,000 spinal fractures and 300,000 hip fractures, a leading cause of nursing-home admissions. Women, who lose bone rapidly at menopause, are far more susceptible than men. An estimated 50 percent of women and 25 percent of men over age 50 will suffer an osteoporosis-related fracture in their lifetime.”

The issue is only going to get more urgent as the aging population increases. In 2010, the number of people with osteoporosis was estimated at 12 million, according to the NOF. Experts predict that number will increase to 14 million by 2020 if additional efforts are not made to prevent and effectively treat the disease. And by 2025, the NOF says, “it is predicted that osteoporosis will cause about three million bone fractures and cost the health care system more than $25 billion each year.”
Treating the condition
As with all medications that you take—for example, high blood pressure medication—you take the medication to treat your condition. It doesn’t cure your high blood pressure; it simply treats it by bringing it down to a normal level. However, if you go off your blood pressure medication and have not changed your lifestyle (i.e. weight loss or lower sodium intake), what would happen? Your blood pressure would more than likely be right back where it started.

The same thing happens with osteoporosis medications. Once you stop taking them for a period of time, your bones will resume their abnormal turnover rates that caused you to seek treatment in the first place.

The Wall Street Journal’s Beck reports that medications—used by the right women, in the right way—have significant advantages. She quotes Dennis Black, a University of California, San Francisco epidemiologist who led the clinical trials for two bisphosphonates, Fosamax and Reclast, and consults for companies that make osteoporosis drugs: “I would hate to see those advantages lost,” he says.

Setting the record straight
In today’s world of immediate access to information, we often hear only the horror stories associated with medications. It would be nice if for every story with a negative outcome the press also produced one with a positive outcome, but this is not the case.

The important fact is that medications are developed to heal, they are not meant to harm, but like everything in this world, different people react differently to different stimuli.

Some of us are allergic to nuts, and seafood, and these are natural products. So it is not impossible that someone could develop an allergy or reaction to a man-made product.

Yet, the NOF reminds us that medication remains a vital part of the treatment approach.

“There is widespread belief that—on their own—diet and exercise can reverse osteoporotic bone loss and fractures. This belief is not supported by clinical evidence. In fact, for people with osteoporosis, the so-called ‘drug-free natural approach’ has been shown to increase risk for fracture, disability, dependence, and premature death.”

Determining side effects
One last item to discuss; it is important to know that in conducting research of any type, but especially in drug studies, any adverse event must be reported to the sponsor (manufacturer) of the study. Just to clarify, an adverse event is any event that happens while you are being treated on a drug study.

So let’s say, for instance, you are a participant in a drug study and you weigh 125 pounds when you start the study. As the study progresses the staff notices that you have been gaining weight. By the end of the study you weigh 165 pounds. So the ethical research staff would report that there was a subject who experienced weight gain as an adverse event. If other researchers conducting the same study also report weight gain by their participants, then weight gain is now listed as a possible side effect of this new study medication.

However what you will likely never know is that the study was conducted during the summer months. Perhaps the study participant loved ice cream, and this summer was a hot one, so he/she indulged much more than usual. And perhaps especially high summer temperatures kept the participant inside more and thus physical activity had decreased. These factors could have contributed to the 40-pound weight gain; of course, we do not know that for certain.

When you hear or read about all of the side effects that can be caused by a medication, just know that as ethical researchers we have to report every adverse event whether we feel it is related to the medication or not. At the end of the study the sponsor looks at all of the adverse events, and those that happen frequently become possible side effects. Others that happen once
or twice are often referred to as “less common” side effects. In addition, if someone who was on a study died, let’s say in a car accident, this is still a death and though it’s not related to the medication, it also must be reported. Further, the most feared side effects are exceedingly rare, and they can occur in members of the general population who are not receiving any osteoporosis treatment.

**Bone density screening**

All older Americans, especially post-menopausal women, should have bone density screening by age 65, or earlier if they have additional risk factors such as strong family history, chronic smoking or long-term use of steroid medications.

Dual-Energy X-ray Absorptiometry (DXA) is the gold standard and the only procedure accepted by the World Health Organization for determining bone loss. A T-score of -2.5 indicates a diagnosis of osteoporosis, but this is not the only way physicians determine this diagnosis. If you’ve suffered a low-trauma fracture previously, and have had some bone loss, you may still be diagnosed as having osteoporosis, even if your T-score is >-2.5.

**A positive trend**

The good news is that therapies for osteoporosis are improving. The NOF reports that available therapies for the disease are effective in preventing fractures and can reduce fracture risk by more than 50 percent. More importantly, the NOF says, new medications in the pipeline may further increase bone mass and reduce fractures in older citizens.

The likelihood is low that these therapies will be without risk. As we listen to and read the side effects of new and existing medication, be mindful of what you just learned. The most important take away from this article is this: Everything we do in life contains some form of risk. This may include where you live, the foods you eat, or driving your car. The risk may be immediate, or you may not see it until years later, as in the case of an individual with osteoporosis who suffers a debilitating fracture while on treatment.

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**Then, Now and Tomorrow: Treating Osteoporosis**

Osteoporosis has affected people since the beginning of time. Egyptian mummies from more than 4,000 years ago have been found to have the revealing “osteoporosis hump” and the disease has been depicted in older women in Renaissance paintings.

It wasn’t until the 19th century that osteoporosis was used to describe “porous bone,” when French pathologist Jean Lobstein coined the term from observations in autopsies. In the 1930s, Fuller Albright, M.D., made the first connection between menopause and frail bones, giving the condition a new name—“menopausal osteoporosis.”

**THEN**

The first treatment for women with osteoporosis was menopausal hormone therapy (MHT)—estrogen or a combination of estrogen and progestin.

**NOW**

Since those early days, new medicines have been developed and approved for treating osteoporosis that are helping target the underlying causes of the disease. Current treatments for osteoporosis are either anti-resorptive medicines that inhibit the breakdown of bone tissue, or anabolic drugs that increase the rate of new bone formation.

While these treatments represent significant therapeutic advances, many of them entail strict methods for administering them, which can have serious side effects if taken incorrectly.

**WHAT’S NEXT?**

Researchers are exploring new approaches to attacking the disease based on scientific discoveries that have changed the way they fundamentally look at osteoporosis. Some recent discoveries that are informing research include:

- The identification of a high bone mass gene and its signaling pathway (discovered by ORC investigators)
- The understanding that excess remodeling (the process of bone resorption and bone formation) plays a key role in making bones fragile
- The discovery of biomarkers for the rate of bone remodeling, which can help identify who is at greatest risk from osteoporosis

Adapted from Medicines in Development for Osteoporosis, 2016 Report, courtesy of the National Osteoporosis Foundation.
Creighton University  
Osteoporosis Research Center  
Run & Walk  
Saturday, October 22, 2016  
Register @ 8 a.m. | Start @ 9:30 a.m.  
Lake Zorinsky, Shelter 5, Omaha  
Sign up at creighton.edu/moveit5K
Consider a donation in honor of a loved one to the Osteoporosis Research Center.

Mail this form to:
Creighton Endowment for Osteoporosis
In memory of Sister Anne Evers
601 N. 30th St., Suite 4820
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World-renowned Creighton researcher Heaney recognized on floor of Congress

A professor in the Creighton University School of Medicine was recently recognized on the floor of the U.S. Congress for his dedication to research in the field of vitamin D deficiency.

Robert P. Heaney, M.D., is a researcher in the Creighton University Osteoporosis Research Center, and holder of the John A. Creighton University Professorship. On Nov. 18, Nebraska Rep. Brad Ashford stood before the House of Representatives and lauded Heaney for his life’s work.

“Heis accomplishments speak to his perseverance and commitment to innovation in his field,” Ashford said.

Ashford pointed to Heaney’s commitment not only to osteoporosis research and vitamin D science, but also to Heaney’s work in illustrating for lawmakers the importance of good nutrition for a healthy society.

“He is no stranger to nutrition policy,” Ashford said. “Dr. Heaney helped redefine nutritional requirements by providing the link between malnutrition and long-term health problems.”

Ashford also wished Heaney a happy birthday, as the professor and researcher turned 87 on Nov. 10.

Heaney is a Creighton alumnus, graduating with his bachelor’s degree in 1947 and his medical degree in 1951. He has authored three books and published more than 400 papers, mostly on the field of nutrition and the solutions to vitamin D deficiency, for which he continues to be a global advocate.