

Serious concerns over osteoporosis drugs

OK, first a little context. Those of you who know me via my books, as patients or as radio listeners know that I'm fair when it comes to drugs. Unlike some more doctrinaire advocates of complementary medicine, I am not reflexively opposed to the use of pharmacological treatments or high-tech medicine. As a physician for 25 years, I recognize their benefits, although I realize they are often over-used when preferable natural or low-tech approaches provide safer alternatives.

So that's why I'm especially disappointed that osteoporosis drugs, which I've approached with an open mind over the past decade or so, are now turning out to be so dangerous. I feel taken and burned by my naive lack of skepticism toward them.

Oh, yes, I tried to be "objective" and looked at the medical journal articles that "proved" their efficacy and reassured us about their safety. And, yes, I dutifully prescribed them for many of my patients with bone loss.

But now, I have serious concerns. About the efficacy of many of the meds prescribed for osteoporosis. About their safety. And about the Big Pharma-fueled osteoporosis frenzy that propels women (and men) to gamble their health with risky drugs.

What prompts my reappraisal of current medical strategies for osteoporosis treatment? Take a look at the following:

Is Fosamax (and Its ilk) That Effective?

Studies that prompted widespread adoption of Fosamax (and copy-cat drugs Actonel, Boniva and, most recently, Reclast) showed that it could reduce hip fracture risk by an incredible 56 percent in osteoporotic women, average age 68! But that was **relative risk**. Looking at the data, this meant that in a given year, 99.5 percent of women weren't going to get a fracture; with Fosamax it was 99.8 percent. That's an **absolute risk** reduction of only 0.3 percent. Translation: To save three women from a fracture, 997 women would have to take Fosamax unnecessarily and run the risk of side effects. We used to think the side effects were minimal. Now we're coming to know better.

Bisphosphonate Side Effects

The long-acknowledged side effects of bisphosphonates (Fosamax, Actonel and Boniva) include esophageal irritation, and even ulceration and perforation. Then there's bone aching and the (until recently) thought to be very rare side effect of "BRONJ." BRONJ stands for Bisphosphonate-Related Osteonecrosis of the Jaw, and it involves destruction of the jaw bone with pain, tooth loss, and caving-in of the gums.

Rare Until Recently

A new USC study just showed that of 208 patients who had taken Fosamax pills, nine (4 percent) had active jaw bone decay or osteonecrosis. All the affected patients were women, ranging in age from 63 to 80, who had taken 70 milligrams of Fosamax once per week for 12 to 120 months. And the potential for BRONJ is vastly magnified when osteoporosis drugs are injected, as with Reclast, a newly pitched once-a-year drug.

Esophageal Cancer

Then came a letter to the editor in the *New England Journal of Medicine* that shows that there may be a higher incidence of esophageal cancer in patients taking

bisphosphonates. While not proven, the link makes sense given these drugs' esophagus-irritating effects.

Too Much of a Good Thing?

To top it off, there are new concerns over whether long-term osteoporosis drug use can actually backfire. A new report by researchers at New York's Hospital for Special Surgery notes a series of unusual fractures in bisphosphonate users. Some had virtually no trauma; their bones just seemed to snap. The longer they took the drugs, the worse the risk.

Curious about the study, since my hip fracture was treated at HSS, I looked up the authors: Sure enough, one of the co-authors was my very own orthopedic surgeon, Dr. Dean Lorch. (Mine was the kind that occurred without osteoporosis, the result of a nasty bike crash).

What Do These Drugs Actually Do?

And finally, the latest thing to shake my confidence in bisphosphonate drugs was a recent article in the *New England Journal of Medicine*, which came to an alarming conclusion: We don't really know how these drugs work or how long their effects are maintained. They may harden bone, but they damage key bone cells called osteoclasts—perhaps permanently—with poorly understood long-term consequences. While these concerns do not preclude use of bone-boosting drugs for ALL persons with osteoporosis, they sure make me leery of putting folks on medications at the drop of a hat, which now seems routine in medicine. Additionally, there are a whole lot of natural alternatives available. (For more discussion, see [How Does Dr. Hoffman Treat Osteoporosis?](#))