

# BONE UP/date

OREGON OSTEOPOROSIS CENTER

## Special Edition: *Bisphosphonates and Atrial Fibrillation*

Michael McClung, M.D., Medical Director

May 2008

**Question:** I have heard that osteoporosis drugs such as Fosamax®, Actonel®, Boniva® and Reclast® cause heart problems. Is this really a concern?

**Answer:** A study from Seattle published earlier this week suggested that women who were taking or had taken Fosamax® had an increased risk of developing atrial fibrillation, an irregular heartbeat that can be a serious medical problem. The study compared two groups of patients, one who had atrial fibrillation and a group of patients chosen to be similar but who did not have atrial fibrillation. The study observed that the number of patients taking Fosamax® was greater in those with atrial fibrillation (6.5%) than in group who did not have atrial fibrillation (4.1%). The authors concluded that taking Fosamax® might increase the risk of having atrial fibrillation. However, the two groups of patients (with and without atrial fibrillation) differed in some important ways and probably in some ways that were not measured. For example, the atrial fibrillation group was older by 4 years on average, than the other group. Increased age is known to be a very important risk factor for atrial fibrillation. A similar but very much larger recent study in Denmark compared a group of 13,586 patients with atrial fibrillation with a group of 68,054 patients without fibrillation and found no relationship between atrial fibrillation and the use of Fosamax® or related drugs.

As a result, this study does not prove that Fosamax® increases the risk of atrial fibrillation. The way to answer that question is to take a large group of people and randomly (by chance) give half of them Fosamax® and the other half a placebo and then to see if atrial fibrillation occurs more commonly in the group receiving Fosamax®. That study has been done many times. In one of those many studies, a trend toward more atrial fibrillation in the Fosamax® group compared to placebo was seen, but this difference was not statistically significant. When all of the studies are combined, no effect on atrial fibrillation or any other heart condition is noted more frequently in patients who take Fosamax®.

On the other hand, there is very consistent and strong evidence that treatment with alendronate decreases the risk of spine fractures by 50-65% and hip fracture by 50% in postmenopausal women who have osteoporosis. In such patients, the benefits of taking alendronate or other drugs

in the same family such as risedronate therapy (Actonel®) or ibandronate (Boniva®) are far greater than the possible risk of taking the medicine.

So what do the results of this recent study mean to you?

- 1) *If you are taking Fosamax®:* Don't stop the drug until you have discussed the situation with your doctor. The protection from fractures that treatment provides may go away quickly when treatment is stopped. Furthermore, the possible increased risk of atrial fibrillation with the recent study was seen only in women who had stopped Fosamax® treatment, not in the women who were taking the drug.
- 2) *If you are not on treatment but your doctor has suggested that you start Fosamax® or one of the other drugs:* Consider the likelihood of **experiencing** a known benefit of treatment (protection from fracture) with the unproven risks (atrial fibrillation) or very rare risks (poor healing of jaw after tooth extraction).

No drug is perfectly safe, including such drugs as aspirin, penicillin or even calcium supplements. As in other parts of life, the likelihood of a benefit of any action has to be weighed against the risks of an unwanted affect. Flying to get to Europe has a great benefit compared to the alternatives but is associated with frequent mild side-effects (jet lag, losing luggage) and with rare but serious or even fatal consequences. Thus, to get the benefit of flying, one is exposed to a known set of risks. Deciding about taking any drug has to be considered in the same context. Drugs should not be avoided just because of a possible risk if the benefit of taking the drug far outweighs the likelihood of complications.

**Conclusion:** In my opinion, there is no proof and it is very unlikely that Fosamax® is associated with atrial fibrillation or other heart diseases.

**Disclosures:** Dr. McClung receives research grants and/or consulting fees from Amgen, Eli Lilly, Merck, Novartis, Procter&Gamble, and sanofi-aventis.

*BoneUpdate-RX 05-2008*  
©Oregon Osteoporosis Center, 2008  
5050 NE Hoyt, Suite 651, Portland, OR 97213  
phone (503) 215-6586 fax (503) 215-6428  
[www.orost.com](http://www.orost.com)