

Benefits of osteoporosis treatments outweigh possible risk of rare femoral fractures

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The occurrence of an unusual type of fracture of the femur, or the thigh bone, is very low in patients with osteoporosis, including those treated with the drug family known as bisphosphonates, according to a new study led by a team of UCSF epidemiologists.

While these unusual femur fractures have been reported in case series studies in patients, particularly in those taking [bisphosphonates](#), this UCSF study is the first to examine their occurrence systematically using data from randomized trials, the most rigorous type of study design. The study combined data from three bisphosphonate trials that involved more than 14,000 patients.

The new findings contextualize reports from the American Academy of Orthopaedic Surgeons and news stories on bisphosphonates and femur fractures that have appeared in recent weeks, according to study principal investigator Dennis Black, PhD, UCSF professor of epidemiology and biostatistics.

The study shows that these fractures remain rare even in a population of women who have been taking the drugs for as long as 10 years, said Black, who specializes in [osteoporosis](#) treatment and prevention in post menopausal women. While the risk was not significantly increased among the women taking bisphosphonates compared to placebo, the number of events was too low to definitely rule out a relationship, he said.

The study is scheduled to appear online on March 24, 2010 at NEJM.org and will be published in an upcoming print issue of the [New England Journal of Medicine](http://www.nejm.org).

Bisphosphonates (marketed as Fosamax, Actonel, Boniva, and Reclast) are the most commonly used treatment for postmenopausal osteoporosis. They belong to the class of anti-restorative drugs that act by slowing bone degradation, or desorption, and thereby increase [bone density](#) and reduce the risk of fractures.

The UCSF researchers focused on fractures in the shaft of the femur. Breaks in this region are much less common than hip fractures that occur closer to the top of the bone and are most commonly associated with trauma.

Case reports in recent years have reported femur breaks in patients taking bisphosphonates, occurring with little trauma and having an atypical appearance on x-rays. However, there has been no rigorous large scale study to determine a relationship.

The UCSF study is now the first to do this, using data from the records of a total of 14,195 women who participated in three previous controlled, randomized bisphosphonate trials. The women ranged in age from 65 to 85, and the studies followed them for up to 10 years. There was a total of over 51,000 years of follow up in the three studies combined.

Black's team reevaluated the records for femur fractures in the three trials: two that studied use of oral alendronate (a placebo-controlled phase III trial and randomized extension to 10 years treatment) and one on the use of zoledronic acid (a placebo-controlled trial with the drug infused annually). The trials used similar protocols for original collection and classification of fractures.

In their analysis, the UCSF researchers considered the location of the fracture and compared occurrence in patients who received bisphosphonates versus those who received placebos.

They reviewed records of 283 hip or femur fractures and found a total of 12 fractures in 10 women that were classified as subtrochanteric/diasphyseal femur fractures. They found no significant relationship between bisphosphonate use and increase in risk for these fractures, although the relatively small numbers preclude definitive conclusions, according to Black.

"We found that fractures are very rare, less than 3 per 10,000 years of treatment, even in populations treated for a very long time," Black said. "The trade-off between the risk of this type of fracture and the overall benefit of these medications to osteoporotic patients is striking. The public needs to understand the rare incidence of atypical femoral fractures and the high risk of debilitating fractures in patients with osteoporosis if left untreated. These are important risks and benefits for patients to weigh with their doctors."

He also recommends that patients taking bisphosphonates long term consult their doctors if they experience pain in their thighs, suggesting "It may be time to consider a drug holiday."

Black and his team recommend future studies to assess additional risk factors that could identify a subgroup of patients who might be more vulnerable to rare subtrochanteric/diasphyseal femur fractures.

The UCSF researchers say that an increase of risk might be focused on patients who take other medications such as corticosteroids or other medications that treat osteoporosis such as hormone replacement therapy. They suggest further research include observational studies from population-based registries or healthcare databases that retain

radiographs as useful alternatives.

The three trials that provided data for the UCSF study are the Fracture Intervention Trial, known as FIT; the FIT Long-Term Extension Trial, known as FLEX; and the Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly Pivotal Fracture Trial, known as HORIZON-PFT.

An estimated 10 million Americans have osteoporosis and 34 million more are prone because of low bone density. Patients with significant osteoporosis are at high risk of debilitating fractures: the disease is responsible for more than 1.5 million annually, according to the National Institutes of Health. Only half of people who have lived independently before a hip fracture are able to do so one year later, said Black.

Provided by University of California - San Francisco

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