

## **New task force report on bisphosphonate use and atypical femur fractures in osteoporosis patients**

EurekAlert

Washington, DC, SEPTEMBER 14, 2010 A widely prescribed class of drugs is highly effective in reducing common bone fractures in people with osteoporosis, but an expert panel announced today that these same drugs when used long term may be related to unusual but serious fractures of the thigh bone. In the most comprehensive scientific report to date on the topic, the task force reviewed 310 cases of "atypical femur fractures," and found that 94 percent (291) of patients had taken the drugs, most for more than five years. The task force members emphasized that atypical femur fractures represent less than one percent of hip and thigh fractures overall and therefore are very uncommon.

The task force was convened by the American Society of Bone and Mineral Research the leading scientific organization on bone science in the wake of growing concern about the connection between these drugs, called bisphosphonates, and unusual femur fractures. The Food and Drug Administration (FDA) said in March that it would await the report before making recommendations about bisphosphonates and has received a copy of the task force's report. The report was published in the *Journal of Bone and Mineral Research*.

"For the vast majority of patients with osteoporosis, these drugs are an important weapon against fractures and their benefits far outweigh the risks of using them," said task force co-chair and lead author Elizabeth Shane, M.D., of Columbia University. "Most of the patients who experienced these atypical femur fractures had been taking bisphosphonates for more than five years. However, we are concerned that there may be a relationship between these fractures and long-term bisphosphonate use and, although the risk is low, we want to make sure that people know about the warning signs," she said.

The task force is calling for additional product labeling, better identification and tracking of patients experiencing these breaks, and more research to determine whether and how these drugs cause the serious but uncommon fractures.

The international, multi-disciplinary task force conducted an extensive review of both published and unpublished data and interviewed scientists at pharmaceutical companies that sell the drug and at the FDA, which maintains the MedWatch database that tracks reported side effects of approved medications.

The task force expressed concern about the lack of awareness of atypical femur fractures, their warning signs and their association with long-term use of bisphosphonates. More than half of patients with atypical femur fractures reported groin or thigh pain for a period of weeks or months before fractures occurred, according to the report. More than a quarter of patients who experienced atypical

femur fractures in one leg experienced a fracture in the other leg as well.

Millions of people, primarily women, have been treated with bisphosphonates since they were approved in 1995. Bisphosphonates include the drugs Aclasta, Actonel, Aredia, Bondronat, Boniva, Didronel, Fosamax, Fosavance, Reclast, Skelid, and Zometa. Bone diseases, such as osteoporosis, drastically affect the way people function. Individuals who suffer broken bones as a result of osteoporosis can suffer severe pain, loss of height and stooped posture that can affect breathing and digestion. One in five patients who walked before their hip fracture needs long-term care afterward. And although the rate of hip fractures is two to three times higher in women, after one year, the death rate in men is nearly twice as high.

Among the task force recommendations:

- Product labeling should be changed to alert health professionals and patients to the possibility of atypical femur fractures for patients on bisphosphonate therapy and the associated warning signs; cases should be reported to the FDA MedWatch program.
- New diagnostic and procedural codes should be developed for atypical femur fractures to improve the quality of case reporting and enable better review of medical records.
- An international registry of patients experiencing atypical femur fractures should be established to track cases and facilitate future research.

"We know that bisphosphonates prevent many, many common fractures. For this reason, we want to emphasize that patients should not stop taking these drugs because they are afraid of the much more uncommon femur fractures. They should talk to their health professionals about their concerns and should let them know if they experience any new groin or thigh pain. Patients can also report any side effects of these medications to the FDA by phone or online," Shane said.

"Health professionals should reserve bisphosphonates for patients with certain cancers, Paget's disease of bone, and patients with osteoporosis who are at high risk of having a fracture. Drug labels should include information about this side effect. Although the risks are very low, health professionals should know the warning signs of atypical femur fractures and regularly ask patients on these drugs about groin or thigh pain. They also should assess annually whether this therapy is appropriate for each patient," she added.

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