POPULAR OSTEOPOROSIS DRUGS LINKED TO RARE FRACTURE

Medications designed to strengthen bones might actually raise the risk of a rare type of fracture of the thigh bone, a U.S. panel of experts has concluded. In an announcement released on Tuesday, the panel concluded that bone-strengthening **bisphosphonate drugs**, sold under such names as **Actonel**, **Aclasta** and **Fosamax**, appear to be linked to an increased risk of femur fractures in patients who take the drugs for five years or more.

Bisphosphonates are popular medications, commonly prescribed to women following menopause. They work by slowing down our bones' natural breakdown and turnover process. But in recent years, there has been growing concern about the connection between long-term use of the medications and unusual thigh bone fractures.

The panel was asked to review published and unpublished research on the medications. They also **investigated 310 cases of "atypical femur fractures."** They found <u>94%</u> **of patients who had experienced a femur break had taken bisphosphonates, most for more than five years,** they report in the *Journal of Bone and Mineral Research*.

Lorraine Shackleton, 72, had been on a bisphosphonate medication for seven years when she experienced a leg fracture. She was simply standing on a beach in Brazil, when her leg suddenly gave out. "I sat down. And when I tried to get up, the pain was awful," she told CTV. Doctors in Brazil performed surgery to repair the fracture, but for months that followed, the break didn't heal.

It only began to heal after the dental surgeon told her to go off the drug prior to a tooth extraction. Her dentist told her there was **evidence the drug interfered with bone healing**. Her leg strength began to improve, and X-rays showed new bone being laid down. But she returned to the medication, and the gains disappeared. She is now off the medication, and wants to warn other women. "I just want other women on that drug to be aware of what can happen. I want them to talk to their doctors," she says. "Boy, if I can save another woman two years of being on crutches, it's worth it to me."

The task force members emphasized that atypical femur fractures are very rare; they represent less than one per cent of all hip and thigh fractures. Still, they're urging the U.S. Food and Drug Administration to add a special warning about the risk on the drugs' labelling. The panel stresses that for the vast majority of patients with osteoporosis, bisphosphonates are an important weapon against fractures. The drugs' benefits far outweigh their risks, the panel said.

"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," panel co-chair and lead author Dr. Elizabeth Shane, of Columbia University, said in a news release. She added that her panel wants to emphasize that patients should not stop taking these drugs because they are afraid of these rare femur fractures. They should instead talk to their doctors about their concerns and should let them know if they experience any new groin or thigh pain.

Dr. David Sanders, an orthopedic surgeon London Health Sciences Centre, says he's seen a number of atypical femur fractures, as have most of his colleagues across Canada, but he wonders how many are getting missed. "*There is a lot of concern in the orthopedic community* ... that we are catching the tip of the iceberg," he told CTV News.

The task force expressed concern about the lack of awareness of the warning signs of femur fractures. They note that more than half of patients with the fractures reported groin or thigh pain for a period of weeks or months before the breaks occurred. And more than a quarter of patients who experienced atypical femur fractures in one leg experienced a break in the other leg as well.

Dr. Robert Josse, a member of the scientific advisory council of Osteoporosis Canada notes that more study is needed to determine if and how bisphosphonates cause the fractures. "The exact cause for these unusual atypical fractures is still uncertain and more research is needed to identify who is at risk and why these fractures occur," he said.