



Statement

Long-Term Use of Bisphosphonates

March 12, 2010

There have been a number of stories in the media in recent days that have suggested a potential link between the long-term use of bisphosphonate medications (Fosamax, Actonel, Boniva, and Reclast), which are indicated for the prevention and treatment of osteoporosis, and an increased risk for an unusual type of leg fracture called a subtrochanteric femoral shaft fracture. Although these news reports have generated concern among patients and health care providers, there is currently no conclusive evidence demonstrating that bisphosphonates cause this rare type of fracture.

Subtrochanteric fractures in patients taking bisphosphonates were initially reported several years ago. In June 2008, the US Food and Drug Administration (FDA) reviewed all available case reports and clinical trial data and found no increased risk of these atypical fractures in patients taking bisphosphonates, a finding that was reiterated in a March 10, 2010 FDA release. Additionally, observational studies have found that the risk of subtrochanteric femoral shaft fractures compared to osteoporotic hip fractures is similar in patients with osteoporosis whether they were taking bisphosphonates or not.

It is important to emphasize that many studies have confirmed the effectiveness of bisphosphonates in reducing the risk of fractures in patients with osteoporosis. The data available at this time suggest that the potential risk of subtrochanteric fractures is very low (>1 in 10000). Since patients taking bisphosphonates have osteoporosis and are at high risk for suffering the more typical osteoporotic fracture, patients and their health providers must weigh the risk-benefit ratio of ongoing therapy with bisphosphonates. For most patients, the benefits of therapy in leading to osteoporotic fracture reduction will outweigh the potential risks of developing this rare type of femur fracture.

The Endocrine Society encourages patients to discuss these issues and any concerns they have with their medication with their health provider. Healthcare professionals should continue to follow the recommendations in the package insert when prescribing bisphosphonates. Patients should continue taking their medication unless advised to stop by their health care provider, and should continue to pay careful attention to factors related to fall prevention. Health providers and patients should report any adverse events associated with the use of bisphosphonates to the FDA MedWatch program.

For additional information, please contact Holly Whelan, Associate Director of Health Policy, at hwhelan@endo-society.org.