

Study finds one-third of women taking bisphosphonates remain at risk for fracture

June 6 2016

More than 53 million Americans age 50 and older, primarily women, have osteoporosis or are at high risk for the condition due to low bone density. A recent study of oral bisphosphonates, the most commonly prescribed osteoporosis treatment, found that approximately a third of women prescribed these drugs continue to be at elevated risk for bone fracture, an outcome that may have several origins.

Oral bisphosphonates are a pillar of [preventive treatment](#) for patients with osteoporosis and have been shown to be effective in reducing the risk of disabling [bone fractures](#). It is known from clinical trials that no medication completely eliminates the risk of fracture. Additionally, medication effectiveness may be different in [clinical practice](#) compared to well-controlled research trials.

Research from the Regenstrief Institute-Merck (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.) collaboration suggests that many women still have indicators consistent with higher risk of fracture while taking these medications. The cross-sectional population health study was based on a retrospective database analysis of 7,435 women age 50 and older taking bisphosphonates for at least two years during the 2000-2012 time period. The analysis was published in the peer-reviewed journal *Bone*.

"While we found that a substantial proportion of patients who took oral bisphosphonates remain at risk for hip, spine, and other major fractures, this class of drug does improve bone density in the majority of patients

and should remain a mainstay of osteoporosis management," said Erik Imel, M.D., the Indiana University School of Medicine endocrinologist and Regenstrief Institute-affiliated scientist who led the study.

"We limited our study to patients who were considered to be compliant with taking their medication, based on drug dispensing days covered, with the presumption being that those who filled prescriptions took the medication properly. We would expect even less benefit if patients fail to take their medication properly. To increase treatment effectiveness, patients and their doctors should be vigilant that the drug is taken reliably and properly. However, osteoporosis drugs are not enough. Physicians and their patients are well advised to discuss additional important modifications to decrease fall risk and fracture risk. These include exercise, smoking cessation, use of assistive devices such as canes or walkers, modifying the home to avoid obstacles that might lead to falls, and taking appropriate amounts of vitamin D and calcium."

Conducted under the auspices of a Regenstrief Institute-Merck collaboration, the retrospective cohort study utilized anonymized data from the Indiana Network for Patient Care, a health information exchange founded by the Regenstrief Institute. The study authors note that the data they used reflects real-life medical practice and patient behavior from a wide range of physicians and patient backgrounds. Adherence to bisphosphonate therapy was determined by prescription fulfillment records. Clinical data included information on bone density and fractures.

"We know that taking bisphosphonates decrease fracture risk compared to those not taking these drugs," Dr. Imel said. "But what about those women who weren't getting the anticipated benefit and are not improving bone density or even are losing [bone density](#)? What predicted that? The purpose of this study was to focus attention on those not doing well, in order to begin to decrease the odds of future fractures in this

large group of vulnerable patients.

"Not everyone responds the same way to oral bisphosphonates or any drug. Various factors could convey continued risk of fracture in spite of bisphosphonate therapy, including other medical problems and risk factors for falling. Since we know that such a high percentage of women continue to have elevated fracture risk we—doctors and patients—need to focus on these factors," Dr. Imel said. "For example, we found that women who had other medical conditions in addition to [low bone density](#)—a frequent occurrence in this older population—had higher fracture risk. Taking some medications in combination with bisphosphonates seemed to increase [fracture risk](#). However, having more medical conditions and taking more drugs are most likely markers of heightened risk rather than causative factors."

Neurologic problems, often linked to heightened risk of falls, as well as inflammatory and other chronic joint conditions including arthritis were found to be associated with higher odds of having a fracture among those taking bisphosphonates.

"I always tell my osteoporosis patients, 'Don't fall,'" said Dr. Imel. "They usually chuckle, and then we talk about things they can do to decrease the risk of falling, including proper footwear and assistive devices. Many patients are reluctant to use a cane or a walker. I try to get them to understand the importance of using any tool that decreases the chance of falling."

Provided by Indiana University

Citation: Study finds one-third of women taking bisphosphonates remain at risk for fracture (2016, June 6) retrieved 11 July 2024 from <https://medicalxpress.com/news/2016-06-one-third-women-bisphosphonates-fracture.html>

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