



COPING
'A newsletter from COPN'
September 17, 2010
Remember: You can live well with
osteoporosis!

If you have received this newsletter from the Canadian Osteoporosis Patient
Network (COPN)
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Thought for Today - *"Each day is a new day to start over and be a better person than yesterday."*

HEALTH CANADA Approves PROLIA™ (Denosumab) as New Choice in Osteoporosis Therapy

Amgen Canada announced on September 8 that Health Canada has approved Prolia™ (Denosumab) as another treatment choice for osteoporosis patients. Prolia is approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as having a history of osteoporotic fracture or multiple risk factors for fracture) or who have failed on other osteoporosis therapies or are intolerant of other available therapies. Prolia inhibits the development and activation of osteoclasts (the cells that clear away older bone)

while increasing bone mass and bone strength. As a result, the risk of breaking bones at the hip, spine and non-spine sites is reduced while taking Prolia.

Prolia is now available to patients in Canada with a prescription from a physician and is administered by a trained healthcare professional once every six months as an injection under the skin.

Clinical Trial Results

Health Canada's approval of Prolia is based on a study involving 7,808 postmenopausal women with osteoporosis. In this study comparing Prolia to placebo, treatment with Prolia resulted in greater bone mass, stronger bones, and a significantly reduced risk of important osteoporotic fractures such as those of the spine, hip and other sites

Safety Information

The most common side effects of Prolia as seen in the clinical trial were pain in the muscles of the arms, legs or back and a skin condition with itching, redness and/or dryness. Osteonecrosis of the jaw has been very rarely reported in patients treated with Denosumab (Prolia) or bisphosphonates. It is important that patients taking Prolia continue to take adequate calcium and vitamin D.

At COPN, we are pleased to see another treatment alternative for osteoporosis patients. As with any medication, you should decide with your doctor which treatment best suits you.

For more information on Prolia, including the results of the Clinical Trial, visit Osteoporosis Canada's website at www.osteoporosis.ca.

Atypical Fractures and Bisphosphonates

There have been a number of news reports on "atypical" femoral fractures in the past few months suggesting that some osteoporosis medications are causing fractures rather than preventing them.

The major problem in osteoporosis is fractures (broken bones). Without proper treatment, patients with osteoporosis are more likely to fracture. The most common osteoporotic fractures are those of the hip, spine, wrist and shoulder. Hip fractures occur in the upper part of the thigh bone - a bone which is called the femur. So a hip fracture is also called a femoral fracture. Femoral (or hip) fractures are commonly associated with osteoporosis and often occur before any treatment has been started. In fact, the occurrence of a hip fracture is one of the ways in which osteoporosis can be diagnosed.

What are "typical" femoral fractures?

A “typical” femoral fracture:

1. Occurs in a person who has osteoporosis.
2. Usually occurs after a fall when the hip breaks as a result of hitting the ground.
3. Some patients with osteoporosis may break one hip and some time later, may fall again and break the other hip.
4. Has no advance warning signs – the hip doesn’t hurt before it breaks.
5. Occurs very high up on the femoral bone, very close to the hip joint.
6. May happen to a patient before or after he/she starts taking osteoporosis medications. Some patients break a hip because they have undiagnosed (and untreated) osteoporosis. Others are on treatment for their osteoporosis, but we do not have perfect drugs so sometimes the medication fails to prevent the hip from breaking when the person falls.

What are “atypical” femoral fractures?

An “atypical” femoral fracture:

1. The fracture can occur without a fall. The femur can just snap and then the person falls.
2. Pain is often a warning sign. In one study, seventy percent of the patients who suffered “atypical” femoral fractures reported pain in the thigh or in the groin which had been present for weeks or months before the fracture.
3. The fracture occurs lower down from the hip, closer to the middle of the femur.
4. Sometimes, x-ray findings can be seen even *before* the femur breaks. In about 25% of cases, both of the femurs show x-ray changes suggestive of developing “atypical” femoral fractures.
5. In most of the “atypical” fracture cases that have been seen, the patients are on bisphosphonate medications (usually for longer than 5 years). This is what first made doctors suspect that there *may* be a connection between bisphosphonates and “atypical” femoral fractures.

Bisphosphonates are a very common family of medications used to treat osteoporosis. They include alendronate (Fosamax/Fosavance), risedronate (Actonel) and zoledronic acid (Aclasta).

How does an “atypical” femoral fracture happen?

Try to think of an “atypical” femoral fracture as a crack in your windshield. It starts off as a little tiny crack and then very slowly works its way across. That little crack can cause pain. Slowly, the crack makes its way around the bone and

when it reaches a certain point – SNAP – the weakened bone breaks for no apparent reason.

Currently, we don't understand why these fractures are happening in some patients. Is it due to their osteoporosis? Is it related to the treatment and, in particular, to bisphosphonates, especially when used for many years? We don't know. We also don't know why the "atypical" fractures occur only in the femoral bone.

I'm on a bisphosphonate. So what do I do now?

Before you throw away your osteoporosis medication, you need to know ALL the facts. "Typical" femoral fractures due to osteoporosis are very common. The great majority of hip fractures are of the "typical" kind. "Atypical" femoral fractures, on the other hand, are rare events and account for **less than 1%** of all femoral fractures.

If you have osteoporosis and are at high risk for fracture, you are much more likely to suffer a "typical" femoral fracture if you are not treated than you are of ever getting one of these rare "atypical" femoral fractures if you are on medication. The bottom line is, if you have an increased risk of fracture, the benefits of bisphosphonates far outweigh the risks. In other words, bisphosphonates still remain very good medications for those who need them.

It is always wise to monitor your own health. If you are on a bisphosphonate because you are at increased risk of fracture, you should be aware of the warning signs of a possible "atypical" fracture. If you develop pain in your thigh or groin that is persistent for weeks, *make sure you mention this to your doctor*. Some simple tests (regular x-rays or a special type of bone scan) may show whether or not you are developing one of these "atypical" femoral fractures. Sometimes the problem can be diagnosed *before* the bone breaks.

While there are many unanswered questions about "atypical" femoral fractures, we can still draw several conclusions:

- "Atypical" fractures of the femur are rare
- Bisphosphonates are still an effective treatment for osteoporosis.
- The benefits of taking these medications far outweigh the risks in most patients with osteoporosis.
- If you have concerns, you should discuss them with your health care provider(s).
- More research is needed in this area.

You can count on COPING to bring you scientifically credible, objective news about any new developments in the field of osteoporosis. Finally, please remember to talk to your doctor before making any changes in your medication.

Funny bone – If swimming is so good for your figure, how do you explain whales?

Notices/references

i. Remember: It is important for you to eat a healthy diet, get some appropriate exercise, take your calcium and vitamin D and if your doctor has prescribed a medication don't forget to take it as directed.

ii. COPING Weekly will come to you every second Friday. We hope you enjoy it and find the information useful. Don't forget to log on to www.osteoporosis.ca for up-to-date information.

iii. The material contained in this newsletter is provided for general information only. It should not be relied on to suggest a course of treatment for a particular individual or as a substitute for consultation with qualified health professionals who are familiar with your individual medical needs. Should you have any health care related questions or concerns, you should contact your physician. You should never disregard medical advice or delay in seeking it because of something you have read in this or any newsletter.

iv. To have your name removed from the COPN mailing list please contact us at the email below.

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