

OSTEONECROSIS OF THE JAW (ONJ): INFORMATION FOR CANCER PATIENTS

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THE BONE AND CANCER FOUNDATION**



1. Q. What is osteonecrosis of the jaw (ONJ)?

A. Osteonecrosis of the jaw (ONJ) is a rare dental condition. It is an area of exposed jaw bone (top jaw bone or bottom jaw bone) that shows no sign of healing after 8 weeks of appropriate dental treatment. ONJ is much more likely to occur after an invasive dental procedure, such as a tooth extraction, implant surgery or other procedure has been performed. The gum over the affected area no longer covers the bone and the underlying bone is exposed. There may be pain or numbness in the affected part of the mouth.

2. Q. Why should cancer patients who are taking intravenous bisphosphonates or denosumab (See question 6) be concerned about ONJ?

A. Over the past few years, most of the cases of ONJ that have been reported were cancer patients who were treated with intravenous bisphosphonate drugs, mainly pamidronate (Aredia®) and zoledronic acid (Zometa®). There is concern, but no proof, that these bisphosphonate drugs cause ONJ. Many of the affected cancer patients were also treated with chemotherapy and steroid hormones and these treatments could also be risk factors for ONJ.

3. Q. What are bisphosphonates?

A. Bisphosphonates are drugs which suppress abnormal bone resorption. These drugs can be given by mouth or by intravenous infusion. When the drugs are taken by mouth only a small amount of the drug enters the blood and gets to the bone. When the drug is given by intravenous infusion, about half of the drug goes to the bone. Because abnormal bone resorption is much greater in patients whose cancer has spread to the bone than in patients with osteoporosis or Paget's disease, cancer patients usually are treated with an intravenous bisphosphonate.

4. Q. What is the difference between the two drugs pamidronate (Aredia®) and zoledronic acid (known as Zometa®, Aclasta® and Reclast®)?

A. Zoledronic acid is stronger than pamidronate. Both drugs are approved by the U.S. Food and Drug Administration (FDA) for treating patients whose cancer has spread to the bone. Reclast® and Aclasta® (other names for zoledronic acid) are also approved for treating Paget's disease and osteoporosis. (Aclasta® is the drug name used outside the U.S. and Reclast® is the name used in the U.S.).

5. Q. Should patients who do not have cancer be concerned about taking bisphosphonate drugs because of the risk of developing ONJ?

A. Probably not. Many osteoporosis and Paget's disease patients have taken these drugs. Only an extremely small number of the osteoporosis and Paget's disease patients who have taken bisphosphonates have ever developed ONJ.

6. Q. What is denosumab?

A. Denosumab (Xgeva™) is a drug that prevents drug breakdown or resorption by inhibiting

RANKL, a protein that activates osteoclasts, the cells that are involved in bone breakdown or resorption. Denosumab has also been associated with ONJ. Since the bisphosphonate drugs and denosumab both block bone resorption it is possible that strongly blocking bone resorption may cause ONJ.

Denosumab is given by subcutaneous (under the skin) injection every four weeks and can be used with standard anti-cancer therapy.

7. What should cancer patients being treated with bisphosphonates or denosumab do about dental care?

- A. All patients who are going to be treated with bisphosphonates or denosumab should have a routine dental exam and be in a regular program of good oral health. Their oral health program does not have to be any different from what is recommended under normal circumstances for patients who are not being treated with bisphosphonates or denosumab.

If a patient needs to have extensive dental work or oral surgery, it is best if the bisphosphonate or denosumab treatment be delayed until the dental work is done. If dental or oral surgery is needed, the dentist should be told that the patient is taking bisphosphonates or denosumab. The dentist can then choose the least invasive procedure.

In patients being treated with an intravenous bisphosphonate drug, the drugs stay in the bone for a very long time. So, even if the bisphosphonate treatment is stopped, the drugs will remain in the bone.

8. Q. What should patients do if they develop ONJ?

- A. There are no specific treatments for ONJ. Currently, patients are treated with germ-fighting mouthwashes and antibiotics. Antibiotics work for some patients, but not for all. Bisphosphonate treatment is usually stopped if the cancer is under control. If the cancer in the bone is very active, the patient and the doctor must decide if the bisphosphonate should be continued or restarted.

There is no information that clearly shows that stopping bisphosphonates or denosumab helps ONJ or if continuing the drugs makes ONJ worse.

Some patients with ONJ have developed new areas of ONJ when the bisphosphonates are restarted; however other patients in the same situation have not developed new areas of ONJ and have healed their areas of exposed bone.

The mission of The Bone and Cancer Foundation is to:

- Provide information to cancer patients and family members on the causes and current treatment of cancer that involves the bone;
- Provide information and serve as a resource for physicians, nurses and other health professionals regarding the management of cancer that spreads to the bone.



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