

Researchers determine how often cancer patients develop osteonecrosis of the jaw

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A landmark study by researchers from the SWOG Cancer Research Network, a cancer clinical trials group funded by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), has found that 2.8 percent of patients on average develop osteonecrosis of the jaw, or ONJ, within three years of starting a common treatment for cancer that has spread to the bone.

Appearing in *JAMA Oncology*, the findings are important because the treatment, zoledronic acid, is prescribed to tens of thousands of [patients](#) whose [cancer](#) has spread to the bone. Almost all forms of cancer can spread, or metastasize, to bone but the most common are lung, breast, and prostate cancers and multiple myeloma. Zoledronic acid can protect bone, but is associated with a risk of ONJ, which causes exposed bone in the jaw that does not heal. This causes inflammation and pain in the mouth, and people with ONJ may have trouble speaking, eating, and smiling—small everyday acts that play a big role in patients' [quality of life](#).

No prior studies had reliably determined how common ONJ is. The SWOG study is the first, and largest, to follow cancer patients over time to determine the incidence of ONJ as well as its [risk factors](#). It was conducted by SWOG through the NCI's National Clinical Trials Network and its NCI Community Oncology Research Program.

Catherine Van Poznak, MD, the co-chair of the study, known as S0702, and a breast cancer physician at the University of Michigan Rogel

Cancer Center, said an estimated 280,000 adults in the U.S. live with metastatic bone disease. If they're all treated with zoledronic acid, according to S0702 findings, about 7,840 will develop ONJ in three years.

"Until now, we've never had good estimates of how many cancer patients get ONJ, and we've found that while a small percentage develop the condition, a significant number of people are at risk of being affected," Van Poznak said. "It's important for physicians and patients to have a better understanding not only of the incidence of ONJ, but what the risk factors are and how it impacts patients."

Bone health is a major issue in cancer care, and zoledronic acid is the most frequently prescribed protective agent to treat bone metastases. The drug is beneficial because it reduces cancer's ability to break down bone, a process that unfortunately also can cause fractures, pain, and other complications.

Van Poznak and her SWOG colleagues wanted to understand ONJ better, and launched S0702, a large-scale, prospective study designed to determine the incidence of the disease in cancer patients and to learn more about risk factors and impact on quality of life.

A total of 3,571 participants from 172 sites were registered onto the trial, and 3,491 patients were evaluated in the final results. All had metastatic [bone](#) disease and were prescribed zoledronic acid within 30 days of joining the study. Most of the patients had breast, prostate, lung cancers or multiple myeloma. In the study, medical, dental, and patient-reported outcome (PRO) forms were collected every six months. If patients were diagnosed with ONJ while participating in the trial, the dental exam was conducted and the paperwork was submitted every three months. Patients were followed for three years.

The key findings:

- Among the 3,491 patients analyzed, 90 cases of ONJ were confirmed. The estimated cumulative incidence of confirmed ONJ at three years was 2.8 percent. At three years, the highest ONJ rates were among multiple myeloma patients and lowest among breast cancer patients.
- Those most at risk for ONJ had pre-existing poor dental health, as defined by missing teeth, dentures, or prior oral surgery. Smokers were more likely to develop ONJ. Patients who received zoledronic acid in shorter dosing intervals—every five weeks or less—also were at greater risk for getting ONJ.
- Participants who developed ONJ reported a much worse quality of life based on oral health symptoms such as pain.

Van Poznak said the findings may provide evidence to support less frequent use of [zoledronic acid](#)—such as every 12 weeks—to reduce the risk of [cancer patients](#) developing ONJ.

Provided by SWOG

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