

Denosumab superior to zoledronic acid for breast cancer patients with bone metastases

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Treatment with denosumab resulted in a greater reduction in skeletal-related events in patients with breast cancer that spread to the bones compared with zoledronic acid, while also maintaining health-related quality of life, according to the results of a phase III study published in *Clinical Cancer Research*.

"Our data indicate that denosumab should be the treatment of choice for the [prevention](#) of skeletal-related events and hypercalcemia in patients with [breast cancer](#) that has metastasized to the [bone](#)," said Miguel Martin, M.D., Ph.D., professor of medicine and head of the [Medical Oncology](#) Service at Hospital General Universitario Gregorio Marañón in Madrid, Spain.

Bone metastases can have devastating consequences for breast cancer patients including hypercalcemia, bone fractures, spinal cord compression and more, according to Martin. The introduction of bisphosphonates, such as [zoledronic acid](#), into the clinic has delayed the onset of these skeletal-related events. However, the use of these drugs is associated with acute reactions and kidney toxicity. Denosumab has a mechanism of action that is more specific than zoledronic acid, and it does not cause these adverse events.

Martin and colleagues have previously reported the [phase III](#) study results indicating that denosumab is superior to zoledronic acid in preventing skeletal-related events in women with breast cancer and bone metastases. In the study, they randomly assigned 2,046 patients with

breast cancer to receive subcutaneous denosumab and intravenous placebo, or intravenous zoledronic acid and subcutaneous placebo. In their current analysis, the researchers further analyzed the data from that study to get more information about bone-related complications and [quality of life](#).

The data indicated that only 31 percent of patients on denosumab experienced a skeletal-related event compared with 36 percent assigned to zoledronic acid. Among those who experienced a skeletal-related event, few patients assigned denosumab experienced a second event while enrolled in the study.

Treatment with denosumab reduced the need for radiation therapy to the bone by 26 percent, and those patients also had an 18 percent lower risk for developing a skeletal-related event or hypercalcemia of malignancy. Quality of life also improved. In addition, patients assigned to denosumab had fewer acute phase reactions associated with a flu-like syndrome and fewer adverse events related to kidney dysfunction compared with those assigned to zoledronic acid.

"This analysis provides additional evidence of the superiority of denosumab over zoledronic acid," Martin said. "The clinical implication of this analysis is clear: Denosumab offers an improved therapeutic index with respect to the prior standard."

Martin and colleagues plan to continue to evaluate the use of denosumab to prevent bone-related issues in cancer patients. Due to the drug's ability control the bone microenvironment and to curb the growth of breast cancer cells, they are also testing denosumab as a preventive adjuvant therapy for early breast cancer patients.

Provided by American Association for Cancer Research

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