

## Women with metastatic breast cancer can safely receive bisphosphonates less frequently, without comp

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Women with metastatic breast cancer to the bone may be able to receive bisphosphonates, the bone-targeting class of drugs like zoledronic acid, less often after the first year of monthly administration. With that practice change, women may also reduce their risk of serious side effects, according to a study led by researchers at The University of Texas MD Anderson Cancer Center.

The research was presented today on the press program of the American Society of Clinical Oncology 2014 Annual Meeting by MD Anderson's Gabriel Hortobagyi, MD, professor, Breast Medical Oncology.

Hortobagyi will also present the data in an oral presentation on Monday. The study found that receiving zoledronic acid every 12 weeks after one year of monthly administration was as efficacious as continuing to receive it monthly.

Findings from the OPTIMIZE-2 study could have an impact not just in the setting of [metastatic breast cancer](#), but other solid tumors, as well as multiple myeloma, where monthly intravenous [bisphosphonates](#) are used to prevent skeletal related events and the loss of bone mass.

According to the American Cancer Society, 232,670 women will be diagnosed with breast cancer in 2014 and 40,000 will die from the disease. The overwhelming majority of metastatic [breast cancer patients](#) will develop a bone metastasis at some point during their care, says

Hortobagyi.

MD Anderson has a long history of research discoveries with bisphosphonates. In the 1990s, Hortobagyi and Richard Theriault, D.O., authored the practice-changing publications in metastatic breast cancer showing pamidronate's association with fewer skeletal-related events (SRE)—including bone fractures and bone pain, and spinal cord compression – leading to the incorporation of the drug class into the metastatic disease management.

"With those findings, it became standard of care to continue bisphosphonates for the life of the metastatic breast cancer patient. Yet there were no definitive studies or guidelines confirming this clinical practice or looking at long-term side effects," said Hortobagyi, the study's national principal investigator.

"The OPTIMIZE-2 trial is the largest study designed to date looking at the frequency of bisphosphonate delivery. The study determined that giving the therapy less often after a year of earlier treatment was non-inferior than receiving the therapy monthly, and we found that less frequency is likely associated with a reduced toxicity," he continued.

The Phase III prospective, double-blind study enrolled 403 metastatic breast cancer [patients](#), with MD Anderson enrolling more patients than any other site. All had previously received nine or more doses of bisphosphonates in their first 10-15 months of therapy. Patients were randomized (1:1) to receive an additional year of 4 mg IV of [zoledronic acid](#), either every month (Q4 wk) or every three months (Q12 wk) for an additional year. Median age was 59 years old, and baseline disease characteristics were similar in both arms. The study's primary endpoint was the number of participants with no more than one SRE. Primary analysis was non-inferiority, with a pre-defined margin of 10 percent.

The researchers found that the SRE rate was comparable in both groups of patients—22 percent in the monthly arm, and 23.2 percent in the every three month arm - indicating less treatment was non-inferior. The researchers also found similar overall safety profile in both arms. However, more kidney-related adverse events were reported in the monthly arm—9.6 percent, compared to 7.9 percent in the every three week arm. Two patients in the monthly arm developed osteonecrosis of the jaw.

The research lets both patients and physicians know that in this case, less may be better than more – a lesson that may extend beyond these findings, says Hortobagyi.

"In general in [breast cancer](#), we're getting to the point where our patients are doing well enough that we can begin to start reducing the treatments they receive, as we're likely over-treating the majority of our patients – and this study is an example of that," says Hortobagyi.

Hortobagyi notes that the study is not without limitations—it focused on patients for one year post-initial bisphosphonates treatment, whereas many patients receive bisphosphonates for the length of their treatment for metastatic disease, even if they develop an SRE, he explains.

Provided by University of Texas M. D. Anderson Cancer Center

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