ONJ Less Than 1% With Bevacizumab

BY BRUCE JANCIN

SAN ANTONIO — The largest-ever analysis of osteonecrosis of the jaw occurring in women receiving the antiangiogenesis agent bevacizumab for advanced breast cancer indicates the incidence is less than 1%, even in patients receiving bisphosphonates.

The analysis involved more than 3,500 bevacizumab-treated women with locally recurrent or metastatic breast cancer prospectively followed in large clinical trials.

As such, it provides a much more accurate—and reassuring—risk estimate than the 16% incidence recently reported by Greek investigators in patients on a bisphosphonate plus bevacizumab (Avastin) or another antiangiogenesis agent, sunitinib (Sutent), for various advanced cancers (Oncology 2009;76:209-11).

The Greek report was a retrospective analysis based on 116 bisphosphonate-treated patients, only a subset of whom were on an antiangiogenesis agent, Dr. Valentina Guarneri noted at the San Antonio Breast Cancer Symposium.

In contrast, she reported on 3,560 patients on bevacizumab combined with a taxane or other standard chemotherapy as first-line treatment for locally recurrent or metastatic breast cancer. The women were participants in the open-label ATHENA study or the randomized RIBBON-1 or AVADO trials.

In the randomized trials, the incidence of osteonecrosis of the jaw (ONJ) was 0.3% in patients on bevacizumab and zero with placebo during follow-up of 10-19 months. In ATHENA, the incidence was 0.4% during 13 months of follow-up of more than 2,200 women on bevacizumab.

The incidence of ONJ was higher in bevacizumab-treated patients with prior or current exposure to bisphosphonates, but not close to the 16% figure cited in the small Greek study. In ATHENA, the incidence of ONJ was 2.4% in bevacizumab-treated patients who had been exposed to bisphosphonates and zero in those who had not.

In the two randomized trials, the rate was 0.9% in patients who had been on a bisphosphonate, compared with 0.2% in those who had not, according to Dr. Guarneri of the University of Modena and Reggio Emilia (Italy).

Detailed analysis of all ONJ cases in this series showed that dental/oral hygiene issues—a recent extraction, a loose tooth, maxillary fracture repair—were present in one-third. Thus, dental examination and avoidance of invasive dental procedures are important in patients on intravenous bisphosphonates, regardless of whether they're on bevacizumab, she added. ■

Disclosures: *This study was funded by F. Hoffmann-La Roche Ltd.*

Combo Tx Improves BMD at Spine, Hip

VITALS

Major Findings: Treatment with teriparatide plus zoledronic acid increased spinal bone mineral density more than either drug alone.

Source of Data: One-year study of 412 postmenopausal women with previously untreated osteoporosis.

Disclosures: The study was sponsored by Novartis, which makes Zometa. Dr. Cosman reported that she has received consulting fees from Novartis and other pharmaceutical companies.

BY KERRI WACHTER

DENVER — Bone mineral density at the spine and hip increased more rapidly and to a greater degree with combined teriparatide and zoledronic acid than with either agent alone in a 1-year study of 412 postmenopausal women with previously untreated osteoporosis.

"Combination therapy could therefore be considered in some patients at high risk for hip and other fractures," Dr. Felicia Cosman said at the annual meeting of the American Society for Bone and Mineral Research.

Clinical fractures were assessed as part of serious adverse event monitoring and were confirmed using radiographic reports. There were 13 fractures in the zoledronic acid (Zometa) group, 8 in the

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