

EFFECT OF ZOLEDRONIC ACID (ZA) ON BONE MINERAL DENSITY (BMD) IN PREMENOPAUSAL WOMEN WHO DEVELOP OVARIAN FAILURE (OF) DUE TO ADJUVANT CHEMOTHERAPY (ADC): FIRST RESULTS FROM CALGB TRIAL 79809.

[512]

Abstract No: 512**Citation:** J Clin Oncol 26: 2008 (May 20 suppl; abstr 512)**Author(s):** C. L. Shapiro, S. Halabi, G. Gibson, D. J. Weckstein, J. Kirshner, W. M. Sikov, E. P. Winer, C. A. Hudis, C. Isaacs, D. Weckstein, R. L. Schilsky, E. Paskett

Background

OF causes accelerated bone loss in premenopausal women receiving AdC of greater magnitude than natural menopause or aromatase inhibitor therapy in postmenopausal women. CALGB 79809 compared the effect of early ZA (with AdC) or late (one year after AdC) on change in BMD in the lumbar spine (LS). We report the effect of early ZA versus no ZA (Control) at 12 months after randomization.

Methods

Eligible women (> 40 years; stages I-III breast cancer; and last menstrual period < 6 months prior to entry) were randomized to either ZA 4 mg IV every 3 months beginning 1-3 months (Arm A) after the start of AdC

or no ZA. BMD of LS, serum FSH, estradiol, and -HCG were performed at baseline (< 28 days prior to randomization) and repeated at 12 months. OF was prospectively defined at the 12 month study visit as > 3 months of amenorrhea with an FSH > 30. All women were told to take 1,000 mg of calcium and 400 IU of vitamin D and compliance (by self-report) and toxicity were assessed every 3 months. Assuming an attrition rate of 20% and that only 50% of women would develop OF, a sample size of 200 per arm was required to have 80% power to detect a mean difference of 0.09 g/cm² in LS BMD at 12 months with at a two-sided significance level of 0.05. A prespecified boundary for early stopping for superiority was crossed at the first interim analysis.

Results

From 12/01 to 12/06, 439 women enrolled and 166 (38%) met the criteria for OF at 12 months. Median age was 47 years (range 40-58); white-92%; performance status 0-91%; stage I-25%; and stage II- 56%. Compliance with calcium and vitamin D was nearly 100%. The majority of ZA-related toxicities were grades 1 or 2; grade 3 included fever- 3%, fatigue-2%, and pain-3%. There was 1(0.5%) woman with possible jaw osteonecrosis after trauma to the jaw and 2 doses of ZA. The results are described in the Table.

Conclusion

ZA adds minimal toxicity and prevents the accelerated bone loss that occurs in women who develop OF receiving AdC. *

A PHASE III TRIAL COMPARING FULV TO FULV + OXALIPLATIN IN STAGE II OR III CARCINOMA OF THE COLON: SURVIVAL RESULTS OF NSABP PROTOCOL C-07.

[LBA4005]

Abstract No: LBA4005**Citation:** J Clin Oncol 26: 2008 (May 20 suppl; abstr LBA4005)**Author(s):** N. Wolmark, S. Wieand, P. J. Kuebler, L. Colangelo, M. J. O'Connell, G. Yothers

Background

We previously reported that FULV + oxaliplatin (FLOX) significantly prolonged 3-year disease-free survival when compared to FULV (ASCO 2005; J Clin Oncol 2007). A secondary endpoint of this

study was overall survival (S) at five years; the data are presented herein.

Methods

Between February 2000 and November 2002, 2,409 eligible patients with

follow-up (1,209 FULV and 1,200 FLOX) with stage II (28.9%) or III carcinoma of the colon were randomized to receive either FULV (5-FU, 500 mg/m² iv bolus weekly x 6; LV, 500 mg/m² iv weekly x

Continued on Next Page