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2.5 cm mass, grade 1-2, estrogen/progesterone receptor positive, HER-2 not over-expressed and excellent performance status. The survey (over the World Wide Web) was designed after reviewing country-specific and international guidelines on breast carcinoma management and consulting with experts to identify areas of controversy.

Results: 39 of 49 breast cancer specialists contacted completed the web-based survey. Seven of the respondents were from England, 11 from France, 9 from Italy, 1 from Germany (excluded for result report) and 12 from Spain. For initial therapy, 36% recommended mastectomy or wide local excision +cosmetic reconstruction or node biopsy, 44% radiation to primary tumor $\pm \mbox{lymph}$ nodes or other sites, 74% chemotherapy, 97% hormone therapy, and 95% palliative care. The most commonly chosen first-line chemotherapy regimens cyclophosphamide+epirubicin+fluorouracil (39%), docetaxel+capecitabine (21%), single agent paclitaxel (21%), and docetaxel+epirubicin (21%). The majority of respondents chose at least one anthracycline (96%) or taxane (82%) based regimen, either alone or in combination as first-line therapy. The most commonly selected second-line therapies included single agent treatment with docetaxel (50%), capecitabine (54%) or vinorelbine (35%). Single agent therapies with capecitabine (48%) or vinorelbine (43%) were the preferred third-line treatments. For hormonal therapy, anastrozole (25%) and exemestane (28%) were the most commonly chosen first and second-line hormone agent respectively. Ninety five percent of respondents recommended palliative care therapies, including counseling (85%), pain specialist (76%), counseling for family/friends (73%), palliative care specialist (64%), and lymphoedema support (61%). Conclusions: This web-based survey of physicians from five European countries found substantial variability in treatment and palliative care preferences for a highly functional, postmenopausal woman who presents with stage IV breast cancer. Participants largely favored aggressive, multimodal treatment, although most indicated that palliative care should be pursued simultaneously.

430 POSTER

Efficacy of ibandronate for the prevention of skeletal-related events in breast cancer patients with metastatic bone disease

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Background: A high proportion of breast cancer patients develop bone metastases that carry a high risk of complications. Ibandronate is a single-nitrogen, non-cyclic bisphosphonate with proven efficacy for reducing the risk of skeletal-related events (SREs). Here, we describe the results of a randomized, placebo-controlled trial to evaluate the efficacy and safety of ibandronate in patients with metastatic bone disease following breast cancer.

Materials and methods: Patients were treated with intravenous ibandronate 6 mg or placebo infused over 15 minutes every 4 weeks for 24 months. The primary efficacy endpoint of the study was the proportion of patients who developed SREs (defined as pathologic fracture, spinal cord compression, radiation therapy or surgery to bone, or change in antineoplastic therapy).

Results: In a group of 150 women with breast cancer and bone metastases, intravenous ibandronate significantly reduced the proportion of patients who experienced an SRE compared with placebo (38% versus 49%; p = 0.028). Time to first SRE was also delayed significantly (median 459 versus 306 days; p = 0.008). A multiple-event analysis showed that ibandronate reduced the risk of developing an SRE by 32% (hazard ratio=0.69; 93% confidence interval 0.42-0.79; p = 0.003). In general, ibandronate was well tolerated, with a renal adverse event profile comparable to placebo and no clinically-relevant changes in serum creatinine levels.

Conclusions: Compared with placebo, ibandronate was associated with significant reductions in the proportion of patients with an SRE, the median time to first SRE, and the SRE risk. The safety profile of ibandronate infused over 15 minutes was similar to placebo, with no evidence of renal toxicity. This study therefore supports previous Phase III trial data for intravenous ibandronate and underlines the efficacy of this treatment for patients with metastatic breast cancer.

431 POSTER

Breast cancer patients with persistently increased bone resorption

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Background: Across all tumor types elevated baseline N-telopeptide (NTX) increases the relative risk of skeletal-related events (SREs), disease progression, and death (Brown JE, et al. *J Natl Cancer Inst.* 2005; 97: 59–69 and Coleman RE, et al. *J Clin Oncol.* in press) in patients with bone metastases from advanced cancer.

Material and methods: Urinary NTX was measured at baseline and at month 3 in 328 breast cancer patients with bone metastases who were treated with monthly 4 mg or 8/4 mg zoledronic acid for up to 24 months (Rosen LS, et al. *Cancer*. 2003; 98: 1735–1744).

Results: At baseline, 132 patients had a urinary NTX ≤ 64 nmol/mmol creatinine (upper limit of normal for premenopausal women) and 196 had elevated baseline NTX (>64 nmol/mmol creatinine). At month 3 of zoledronic acid treatment, 149/196 (76%) of patients who began treatment with elevated NTX had normal NTX (A-N group), 31/196 (15.8%) had persistent elevation of NTX (A-A group) and 16/196 (8.2%) died. Normalization of elevated urinary NTX at 3 months by zoledronic acid (A-N group) was a significant predictor of favorable outcome as measured by total SREs, fracture, and the need for radiation therapy (Lipton A, et al. Proc Am Soc Clin Oncol. 2005). By univariate analysis, high baseline Brief Pain Inventory (BPI) scores, Functional Assessment of Cancer Therapy-General scale (FACT-G) total scores, use of narcotics, and a baseline NTX > 150 nmol/mmol creatinine were all predictive of persistent elevation of baseline NTX levels. Time since cancer diagnosis, prior SREs, antineoplastic therapy, and predominant type of bone metastases (lytic, blastic, or mixed) were not associated with failure to normalize elevated baseline NTX levels. By multivariate analysis, only baseline NTX > 150 nmol/mmol creatinine (P = 0.0036) and use of narcotics (P = 0.011) were independently associated with failure to normalize elevated baseline NTX levels.

Conclusions: After 3 months of treatment with zoledronic acid, 15.8% of breast cancer patients with bone metastases and high NTX at study entry had persistently elevated urinary NTX at 3 months. These patients were at higher risk for SREs compared with those whose urinary NTX was normalized by zoledronic acid treatment. New treatment strategies with zoledronic acid should be investigated in these patients.

Publication

Breast cancer - advanced disease

432 PUBLICATION

Consequences of axillary recurrence after radical breast surgery

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Background: Optimal management for axillary recurrence is poorly understood. The aim of this study was to evaluate the risk factors for overall survival in the patients with axillary recurrence.

Methods: Data of 1098 patients were collected from breast cancer registers from Clinic for Oncology Nis during the 5-years period (1990–1995). The medical data of patients with axillary recurence were reviewed utilizing a standard coding sistem.

Results: All patients underwent modified radical mastectomy. Axillary recurence was diganosed in 43(3.92%) patients. Most patients were presented with a localized, palpable axillary mass 30(69.77%). Cox multivariate analysis of prognostic factors for breast cancer-specific survival showed that node status HR 4.69 (1.50 to 14.72), tumor size HR 3.18 (0.90 to 11.26) and axillary radiotherapy HR 1.99 (0.69 to 5.75) had statistically significant effect on breast cancer mortality. Log-rank (54.21 p < 0.001) analysis showed significant difference for overall survival among women with a axillary recurrence based on different cancer stages.

Conclusions: Tumor size and node status were the most important prognostic factors in women with axillary recurrence.