Results: Treatment with intravenous ibandronate 6 mg or oral ibandronate 50 mg rapidly reduced bone-pain scores and maintained them below baseline levels until the 2-year study endpoint. These reductions were statistically significant compared with placebo (intravenous ibandronate 6 mg, −0.28 versus +0.21, p<0.001; oral ibandronate 50 mg, −0.10 versus +0.20, p=0.001). Analgesic use was also significantly lower with oral ibandronate 50 mg versus placebo (p=0.019). Alleviation of bone pain with intravenous and oral ibandronate was accompanied by significant improvements in global QoL (p=0.004 and p=0.03 versus placebo, respectively). Compared with placebo, intravenous ibandronate also significantly improved physical functioning (p=0.034), emotional functioning (p=0.025) and social functioning (p=0.008), while oral ibandronate 50 mg significantly improved physical functioning (p<0.05) and role functioning (p<0.01).

Conclusions: Treatment with intravenous ibandronate 6 mg or oral ibandronate 50 mg significantly relieved bone pain in patients with bone metastases from breast cancer over 2 years of treatment. Sustained relief of bone pain allowed improved quality of life and mobility. Such benefits have not previously been reported with other bisphosphonates for metastatic bone disease.

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Long-term safety of oral ibandronate in patients with skeletal metastases from breast cancer: 4-year follow-up data

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Background: Long-term tolerability is an important consideration in the selection of bisphosphonates for metastatic bone disease, due to the lengthy duration of exposure needed to prevent bone events and help alleviate bone pain. Ibandronate is a newly approved bisphosphonate for the prevention of skeletal events in patients with breast cancer and bone metastases. The pooled results of phase III clinical trials have shown that oral ibandronate 50 mg once daily for 2 years has a safety profile comparable to placebo in metastatic breast cancer [1]. This abstract reports the results of non-controlled, follow-up studies that were conducted to examine the 4-year safety of oral ibandronate.

Methods: On completion of the 2-year placebo-controlled study period, patients received oral ibandronate 50 mg once daily for a further 2 years (n=115). Adverse events (AEs) and laboratory parameters were recorded.

Results: As might be expected with advanced cancer, 18% of patients did not complete the follow-up period due to AEs, and the majority of patients (83%) experienced at least one AE. Malignancy progression was the most commonly reported AE (52%), leading to the withdrawal of 11% of patients. AEs leading to withdrawal are summarized in Table 1.

Table 1.

	% patients (N)
Any AE	18.3 (21)
Malignancy progression	11.3 (13)
Esophagitis	1.7 (2)
Cerebral infarction	1.7 (2)
Bone pain	0.8 (1)
Back pain	0.8 (1)
Asthenia	0.8 (1)
Ascites	0.8 (1)
Renal AEs	0.0 (0)

Hypocalcemia (n=3), dyspepsia (n=3) and esophagitis (n=2) were the only AEs considered possibly related to oral ibandronate treatment by the study investigators. None of these AEs were serious or led to withdrawal from treatment. Oral ibandronate was not associated with any renal AEs or laboratory/vital sign abnormalities.

Conclusions: Oral ibandronate 50 mg is well tolerated for up to 4 years of treatment, with very few drug-related AEs and no renal AEs reported. These results suggest that oral ibandronate is particularly suitable for long-term administration at home, without the need for close AE monitoring.

References

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Local relapse and systemic recurrence in breast cancer patients. Are they related?

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Introduction: The main problem that still remains unresolved is to define a group of patients for whom local recurrence is a marker or a cause of systemic disease.

Materials and Methods: In order to examine the above mentioned issue we analysed data of 3110 operable breast cancer cases coming from Breast Oncology's Unit registry of IASO Women's Hospital, in Athens. Median follow up period was 52 months (1–344 months). The recorded characteristics are patients age, the type of surgery, the tumor's size and grade, the lymph nodes status, the estrogen and progesterone status, the presence of a lymphatic infiltration and Extended Intraductal Component. To account a systemic recurrence as a consequence of the local recurrence this should have followed in a time period shorter than 12 months. During the follow period we have observed 30 such cases (group 1). On the other hand, 94 patients did not present a systemic recurrence within 12 months after the local relapse (group 2).

Results: The two groups do not differ statistically significant for any of the recorded risk factors. More specifically, mean age was 53.55 and 52.33 years old in the two groups respectively (p-value=0.615). Two (6.7%) and 17 (18.1%) have lymphatic infiltration (p-value=0.157), 11 (36.7%) and 25 (26.60%) patients have EIC (p-value=0.365) in the two groups respectively. The tumor's size in 9 (30%) and 41 (43.6%) cases was 1–20 mm, in 19 (63.3%) and 47 (50.0%) it was 21–50 mm and in 2 (6.7%) and 5 (5.3%) the tumor's size was greater than 50 mm in the two groups respectively (p-value= 0.548). As the lymph nodes status is concerned, no statistically significant difference was found between the two groups (p-value= 0.770). Three patients in group 1 (10%) and 5 (5.3%) in group 2 had a grade I tumor, 17 (56.7%) patients in group 1 and 54 (57.4%) in group 2 had a grade II tumor while 10 patients (33.3%) in group 1 and 32 patients (34.0%) in group 2 had a grade III tumor (p-value= 0.7101). As far as the hormone receptors status is concerned, no significant difference was found (p-values= 0.444, 0.602).

Conclusion: Comparing the two groups with respect to the known risk factors we did not find any significant differences between them. The issue of the relation between local and systemic recurrence remain unsolved and further research is required.

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Zometa® (zoledronic acid) in patients with skeletal metastases secondary to breast cancer – a study of home versus hospital administration

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In patients with breast carcinoma zoledronic acid 4-mg (Z, Zometa®) has been shown to be significantly more effective than pamidronate 90-mg, reducing the risk of skeletal-related events by an additional 30% in patients receiving hormonal therapy (P=0.009) (Rosen et al. Cancer: 2003, 98(8)). It has the further advantage of being administered over only 15 minutes (every 3–4 weeks), allowing the possibility for home administration.

Aim: to compare quality of life (QoL) and pain scores in breast cancer patients receiving Z when administered either at home or in hospital, and to assess the safety of Z by performing serial evaluations of serum creatinine.

Design: breast cancer patients with at least one bone metastasis and receiving hormone therapy were recruited to the study. After a lead-in phase of 3 infusions of Z 4-mg in hospital (to ensure disease stabilisation on hormone therapy), 100 patients were randomised to receive 3 open-label infusions at home or in hospital, to be followed by a further 3 infusions at the opposite venue.

Method: the EORTC QoL scale (QLQ-C30) and brief pain inventory (BPI) were used to assess the potential benefits of Z treatment.

Results: 84 patients completed the study, with 79 available for analysis. Overall global health status, as measured by the QLQ-C30, showed a significant median improvement of 8.3% over the 9 infusions (P=0.0127). According to the BPI, there were significant reductions over the 9 infusions