706 PUBLICATION

Phase II-trial of vinorelbine in 120-hours continuous infusion in metastatic breast cancer refractory to anthracyclines

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Purpose: To evaluate the efficacy and toxicity of vinorelbine in continuous infusion of 96 hours (CI-96) in heavily pretreated patients with metastatic breast cancer refractory to anthracyclines.

Patients and Methods: Between 07-95 and 10-96, 19 patients with metastatic breast cancer (CNS metastasis excluded) refractory to anthracyclines and paclitaxel (progressive disease on treatment or duration of response less than 2 months) received vinorelbine 8 mg/m^2 bolus day 1 and 7 mg/m^2 days 1 to 5. Courses every 21 days for a maximum of 6 cycles in non-progressing patients. 2 patients were found non-eligible. Median age 53 years. Dominant sites of disease were bone (8), visceral (7) and soft tissue (4). 14 patients had received 2 or more previous palliative treatment regimens. Performance status (ECOG) distribution showed PS 0-1-2-3 in 2-7-6 and 3 patients, respectively.

Results: 57 cycles were administered. Objective responses were recorded in 14/17 patients. No CR observed. PR were recorded in 4 patients and No Change in 10 patients. Median TTF was 4.4 months. Toxicity (grade 3–4) was moderate, with mielosupression as limiting toxicity, mainly leukopenia in 66% of patients. Anemia and trombocytopenia were mild. Other significant toxicities included mucositis (27%), peripheral neuropathy (10%), astenia (17%) and drug related fever (17%).

Conclusion: Vinorelbine (CI-96) is an active regimen in heavily pretreated breast cancer patients. Further trials should explore a 4-days regimen restricted to patients with ECOG performance status 0–2 only.

707 PUBLICATION

^{99m}Tc-Tetrofosmin in breast cancer

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Purpose: Tetrofosmin is currently under investigation for its tumor seeking properties. We now evaluated tetrofosmin in 10 patients with breast cancer for sensitivity and specificity in detecting metastatic lesions.

Methods: Ten patients (median age 57 years) were evaluated by tetrofosmin scintigraphy, computed tomography (CT) or magnetic resonance imaging (MRI) for staging of disease. Histology, CT-scans or MRI were used to confirm positive correlation with tetrofosmin scintigraphy.

Results: Tetrofosmin scintigraphy correctly diagnosed breast cancer and metastatic lesions in 89% of patients. There was only one false positive finding. In the patient in whom the primary site of cancer was unknown tetrofosmin scintigraphy showed three consecutive nodules within the left mammary gland in a coronary fashion. Magnetic resonance imaging then confirmed two single nodules of 0.8 cm.

Conclusion: From our results it is evident that tetrofosmin scintigraphy can effectively help detect metastatic disease in soft tissue. The low costs of tetrofosmin scintigraphy and its high correlation with CT scan suggest its use as a screening test for metastatic disease in the restaging process of cancer patients.

708 PUBLICATION

Contralateral breast cancer and distant metastases

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Purpose: To find whether there is correlation of contralateral breast cancer (CBC) with distant metastases.

Methods: In nonrandomised retrospective study we analysed 304 women with breast cancer (January 1985–January 1990). Median age was 53 (28–80). We studied significant differences between group of women with no contralateral breast cancer (NCBC) and women with CBC, according to age, HP type, tumour size, type of breast surgery, Nodal status, Menostatus, Adjuvant therapy, type of radiotherapy and according to particular distant metastases.

Results: Incidence of CBC was 9% (26 pts.). Median time from Breast Surgery to CBC occurance was 60 months (24–144). Among women with CBC, 54% (14 pts.) and among women with NCBC, 40% (112 pts.) had distant metastases. We found correlation between CBC and distant metastases in group of pts. between 46–55 years of age, and in group of pts with postoperative radiotherapy. Pulmonary metastases were found to be more frequent among women with CBC.

Conclusion: There is no statistically significant difference between this two groups of women (CBC and NCBC) (chi square = 1.55144; $p > 0.05$).

709 PUBLICATION

Correlation between the urinary DPD-crosslinks excretion and the course of bone metastases in breast cancer*

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Purpose: Urine/serum sample pairs were collected from 12 patients (pts) with bone metastases from breast cancer in order to correlate the deoxypyridinoline (DPD)-secretion to the clinical and radiological course of the bone metastases under hormonal or cytotoxic and biphosphonate therapy

Methods: DPD-crosslinks were measured by a new chemiluminescent immunoassay with a very good correlation ($r > 0.9$) to the standard high performance liquid chromatography (HPLC). A median of 5 measurements were done at a 3 week interval during a median follow-up of 8 months.

Results: 7 pts were under hormonal, 4 pts under cytotoxic treatment. All pts received pamidronate 90 mg iv q3w. The pts were classified as having progressive (6 pts), stable (5 pts) or regressive (1 pt) bone metastases according to their symptoms and x-rays. 5/6 pts with progressive bone metastases started with DPD-levels below 10 nmol/mmol creatinin and increased to 11–15 nmol/mmol creatinin during progression. All pts with stable disease showed levels between 3–9 nmol/mmol creatinin. Having shown a level of 14 nmol/mmol creatinin before treatment, 1 patient presented complete osteoplastic stabilisation of her lytic processes. She displayed DPD-levels between 6–12 nmol/mmol creatinin during regression.

Conclusions: Using the limit of 10 nmol/mmol creatinin, a clear biochemical evaluation of bone metastases seems to be possible.

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710 PUBLICATION

Docetaxel (D) in combination with amifostine (A) in metastatic breast cancer (MBC): A feasibility and pharmacokinetic study of the EORTC-Investigational drug branch for breast cancer (IDBBC)

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Amifostine is an organic thiophosphate developed as a radio- and chemoprotective agent. A has displayed chemoprotective activity in preclinical studies of paclitaxel (P) + D, and in an early clinical study of P (Schuchter, ASCO 1996). In this ongoing study, the impact of A on the toxicity and pharmacokinetics of D is to be assessed in patients with MBC.

D (100 mg/m^2 q 21 d) is administered as 1st or 2nd line therapy for MBC and combined with A (910 mg/m^2) from the second cycle. Premedication consists of dexamethasone, ondansetron and lorazepam. Toxicity is the primary endpoint. Pharmacokinetics of D are to be performed with and without A (first two cycles). Five patients, of a planned twelve, have been treated to date (total 15 cycles): the regimen is thus far well tolerated with no toxicity related to A. Accrual will be completed in March, at which time efficacy evaluation of A and pharmacokinetic analysis of D will be performed.

711 PUBLICATION

Breast conserving surgery and PDR-Brachytherapy for recurrent breast cancer after primary breast conserving treatment including EBT and HDR-Brachytherapy – Preliminary results

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Purpose: Until now radical mastectomy is commonly performed in case of