S136 Tuesday 23 September 2003 Poster Session

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Characteristics of patients with long-term survival after occurrence of liver metastases from breast cancer

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Background: The occurrence of liver metastases in metastatic breast cancer is related to a significant impairment of prognosis with a median survival between 15 and 19 months. It was the aim of our study to define prognostic parameters for patients with liver metastases, especially to characterize those patients with long-term survival.

Material and Methods: We studied retrospectively n=350 patients with liver metastases from breast cancer. All patients were stratified tollowing the survival after first occurrence of liver metastases in steps of <12 months, 12-24 months, 24-36 months and > 36 months. All subgroups were analyzed regarding clinical, histopathological and therapeutic parameters.

Results: Median survival after occurrence of liver metastases was 20 months, n=66 patients survived longer than 36 months after primary diagnosis of hepatic metastases. Patients with long-term survival were in median younger at age at the time of primary diagnosis of breast cancer as well as at occurrence of liver metastases, compared to all other studied patients (42 years rsp. 45 years versus 48 years rsp. 52 years, p<0,01). None of the patients with long-term survival had ascites at primary diagnosis, 8% showed a hepatomegaly and only 5% were icteric. Liver enzymes were not elevated in 65% and tumor markers only in 61% compared to 76% within all other patients.

Patients with long-term survival showed more often a limited number of metastases (d5) than all other studied patients (52% versus 32%). No differences were found regarding the histological tumor type and the rate of nodal negative patients, ER and PR were positive in 68% and 67% of the patients with long-term survival compared to 54% and 46% of all other studied patients, there were no major differences in HER2-expression, an expression of Ki-67 of > 40% was less often detected in those patients with long-term survival than in all other patients (26% versus 42%).

Conclusions: Younger patients with limited liver metastases without clinical signs of hepatic affection and certain favourable clinical and histopathological pattern seem to have a better prognosis and may be better long-term responsive to multimodal tumor therapy.

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Quality of life (QoL) in patients with metastatic breast cancer (MBC) treated with capecitabine (Xeloda)

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Background: When choosing appropriate therapy for patients with MBC it is important to consider the QoL benefits of oral treatments, such as the novel fluoropyrimidine capecitabine (Xeloda[®]).

Patients and Methods: QoL in women receiving oral capecitabine as second- or third-line therapy for MBC was assessed at baseline, before the first cycle of treatment, at weeks 7 and 13, and at the end of treatment using the EORTC QLQ C-30 questionnaire and the specific model for breast cancer (BR-23). The proportion of patients with an improvement, stabilisation or worsening of QoL scores was determined from week 7 onwards and analysed using generalised linear models for repeated measures. The generalised estimating questions technique and an SAS programme (system version 8.2) were used for the statistical analysis.

Results: 331 patients were evaluated: mean age, 51.1 years (range 28.072.0 years); white/Caucasian (86.7%). Almost 50% of patients completed the questionnaires at all time points. Significant improvements in the following QoL variables were detected: global health status (p<0.0001), role functioning (p<0.0001), emotional functioning (p<0.0001), fatigue (p=0.0006), nausea/vomiting (p=0.007), pain (p<0.0001), insomnia (p=0.001), appetite loss (p=0.0001), constipation (p<0.0001), financial problems (p=0.0004), body image (p=0.0002), future perspective (p<0.0001), breast symptoms (p=0.0003), arm symptoms (p=0.003), sexual enjoyment (p=0.02) and hair loss (p=0.0002). Despite a small worsening of diarrhoea symptoms up to week 7, this was not observed over the whole study. The

proportion of patients remaining stable or improving was between 70 and 80% for most scales. At least 30% of patients reported improvements in the following QoL scales from week 7 onwards: pain (41%); fatigue (39%); emotional functioning (37%); future perspective (37%); arm symptoms (35%); role functioning (34%); hair loss (34%); global health status (33%); cognitive functioning (31%). At the end of treatment, 44% of patients showed an improvement in global health status and 26% had stable scores (QLQ-C30 scale).

Conclusion: In light of its proven efficacy, safety and convenience, treatment with capecitabine has a direct impact on patients' QoL. This important outcome should be considered alongside well-established measures of treatment response (objective response, time to disease progression and overall survival) in patients with MBC.

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Capecitabine and taxanes: combination versus sequential therapy in anthracycline-pretreated metastatic breast cancer (MBC): findings from the Mexican Oncology Study Group (MOSG) phase III trial

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Background: As docetaxel (T), paclitaxel (P) and capecitabine (X) have proven activity, different toxicity profiles and in vitro synergism, they are ideal combination partners for MBC. However, the optimal regimen/schedule has yet to be defined. The aim of this study was to compare the efficacy of sequential X-taxane, XT or XP combination regimens.

Methods: 219 patients with anthracycline-pretreated MBC have been recruited and randomized to receive 3-weekly cycles of X 1,250 mg/m² bid days 114, followed after progression by T 100 mg/m² or P 175 mg/m² day 1 (arm A), X 825 mg/m² bid days 114 plus P 175 mg/m² day 1 (arm B) or T 75 mg/m² day 1 (arm C). With the exception of the proportion having lung metastasis (A, 16%; B, 29%; C, 46%, p=0.003), patient characteristics were similar in each arm.

Results: Response rates in the 177 evaluable patients in arms A, B and C were: CR (29.6% vs 35.4% vs 37.9%); PR (25.9% vs 27.7% vs 34.5%) (A vs C arms OR, p=0.06); SD (11.1% vs 9.2% vs 8.6%). The disease-free period between the end of anthracycline treatment and the start of the trial was predictive for response: <6 months (33% vs 56% vs 69%); >36 months (71% vs 67% vs 91%). Progression-free survival (PFS) was 55% vs 67% vs 71% (A vs C arms, p=0.059) at 6 months and 39% vs 59% vs 59% (p=ns) at 12 months. Overall survival (OS) at 6 and 12 months was: 91% vs 96% vs 86% and 78% vs 80% vs 71%, respectively (both p=ns). Following X monotherapy in arm A, 28/57 evaluable patients had progression (either from the start of the trial or after PR or SD): 43% received T, 11% P, 14% radiotherapy/hormonal therapy and 32% received no further treatment because of rapid tumor progression or patient refusal. Grade 3-4 toxicity for 291, 348 and 342 delivered cycles per arm was: HFS 5.5% vs 3.8% vs 3.6%; mucositis 2% vs 2.1% vs 1.8%; diarrhea 1.8% vs 2.6% vs 1.1%; neutropenia 0.3% vs 0.6% vs 0.3%.

Conclusions: The results indicate a trend towards a higher response rate and PFS with combination treatment, particularly XT compared with sequential X-taxane, although OS was similar in all groups. Because only half of the patients in arm A continued with a taxane following X, X-based combination rather than sequential therapy seems reasonable to be considered upfront. Trial is still ongoing and updated OR, PFS, OS plus quality of life results will be presented during the meeting.

POSTER POSTER

Alleviation of bone pain with oral and intravenous ibandronate in women with metastatic breast cancer

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Background: Up to 80% of patients with advanced breast cancer will go on to present with or develop metastatic bone disease (MBD). Many patients experience severe bone pain, with detrimental effects on patient mobility and quality of life. Alleviation of bone pain is therefore an important aspect of MBD management. The effect on bone pain of ibandronate, a new, highly-potent, third-generation bisphosphonate, has been investigated in phase III trials of patients with MBD from breast cancer.