survival was 18 months (95% CI 12−30). 46 patients were assessable for safety. The incidence of grade 3/4 leucopenia and neutropenia was 20%, respectively 8%. Other observed grade 3/4 toxicities were onycholysis and skin toxicity in 13%, respectively 4% of patients. We observed 2 episodes of grade 3 diarrhea, and 8 infections.

Conclusions: Weekly D and T is an active regimen with a favourable toxicity profile and considerable activity even in heavily pre-treated patients. Several reasons for the inferiority to the q. 3 week schedule can be discussed: 4 patients have failed to be evaluated for response after 10 weeks; a relevant number of heavily pre-treated patients (15%) have been enrolled. Further updates will be presented.

435 Poster

Fulvestrant in metastatic breast cancer previously treated with aromatase inhibitors

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Background: Breast Cancer patients with hormone-dependent disease are frequently treated with Aromatase Inhibitors (AI) in the adjuvant as well as in the palliative setting. In some of these patients Metastatic Breast Cancer (MBC) progression is still responsive to endocrine therapy (ET). Fulvestrant is effective in MBC after AI treatment. Some pre-clinical studies suggest that MBC progression under AI treatment is reversible by adding Fulvestrant (Jelovac et al. Cancer Res 2005; 65: 5439–5444).

In this retrospective study we examined the efficacy of Fulvestrant as single ET agent or combined with an AI in progressive MBC disease after AI treatment.

Material and Methods: This retrospective study included 39 MBC patients with the following characteristics: median age: 65 years (37−89). Previous ET: 3 (1−4); Sites of metastases: bone 69%; skin 23%; Liver 26%; Lung 13%; other 23%. Twenty-two (56%) patients had one site of metastases only (12 had bone metastases) and 17 patients (44%) had >1 site of metastases.

ER, PR and Her-2neu co-expression were analyzed. All patients were ER and or PR positive at the primary tumor.

Efficacy was assessed by Clinical Benefit (CB): stable disease >6 month plus objective remission.

Eight patients (20.5%) received Fulvestrant and continued on the AI previously prescribed for MBC whereas 32 patients got Fulvestran as a single ET agent after AI treatment.

Results: The median time to progression (TTP) was 5.7 months (1−23). CB was observed in 14 patients (35%) – 12 had stable disease >6 months and one had partial remission of skin metastases. In patients with CB the median TTP was 12 months (7−23).

In patients treated with Fulvestrant plus AI the median TTP was 5.4 months compared with a median TTP of 5.7 months in patients with Fulvestrant ET alone.

In 12 patients, metastatic tissue was available for ER and PR expression. The median TTP in 11 patients with ER and/or PR ve+ at metastatic tissue was 4.5 months.

Patients with 2 prior ET had a median TTP of 8 months compared with 5.3 months (3 prior ET) and 4.8 months (4 prior ET).

Conclusions: Fulvestrant may be an effective ET option in MBC after AI treatment possibly providing long-term CB. Our results do not suggest that AI should be maintained in patients eligible for Fulvestran. In a subgroup of patients with metastatic tissue analyzed there was no correlation between ER and/or PR expression at metastatic level and Fulvestrant effectiveness. In our study prior number of ET was negatively correlated with TTP.

436 Poster

New therapeutic options significantly improved overall survival in HER-2-positive metastatic breast cancer patients

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Background: In metastatic breast cancer (MBC), positive HR constitute a favorable prognostic factor and predict response to the hormonal therapy. On the contrary HER-2 overexpression is an adverse prognostic factor associated with a more aggressive tumor. In this retrospective study we analyzed overall survival (OS) of four phenotypes: HR−/HER-2− (triple negative); HR+/HER-2−; HR+/HER-2+ and HR−/HER-2+.

Methods: We evaluated 75 patients with a MBC treated at our Center during 2005. A comparative lecture of estrogenic, progestative and HER-2 receptors was performed by IHC. The 44% of patients had a luminal phenotype, 40.3% patients were HER-2+ and 15.7% patients were triple negative. The median age of patients was 54.8 years (range: 29−70). Localizations of metastatic lesions, Karnofsky Performance Status and the mean of age were similarly in each group. All pts HR+ received at least 2 line of hormonal treatment, all pts HER-2+ received trastuzumab or trastuzumab and lapatinib.

Results: Patients HR+ received on average 3.13 lines of therapy (range, 1−7). Patients HER-2+ on average received 4.09 lines of therapy (range 1−7). Patients triple negative received only 3 lines of therapy (range: 1−4).

At the medium term of follow-up 34 months, no difference in proportion of CNS involvement in both group: HER-2+ and HER-2− (26% vs 27%) were found.

The median of OS for the whole group was 32 months. Any statistical significantly differences in OS was noted in pts with luminal phenotype, HER-2+ or triple negative pts, but a strong trend to decreased a overall survival in triple negative group was noted (24 vs 36 months).

Conclusions: These results suggest that HER-2+ (treated with trastuzumab) and, HR+ metastatic breast cancer pts, have a distinct and favorable biological nature than pts with triple negative. The new option of treatment is definitely needed for this pts group.

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Retrospective analysis of patients with poor prognostic factors and metastatic breast cancer in a phase III study comparing nab-paclitaxel to solvent-based paclitaxel

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Background: Overall, nanoparticle albumin-bound (nab)-paclitaxel demonstrated superior antitumor activity compared with solvent-based paclitaxel in a phase III trial of patients with metastatic breast cancer (MBC). The efficacy of nab-paclitaxel in patients with poor prognostic factors was examined in the current analysis.

Material and Methods: This was a retrospective analysis of a multicenter, randomized, phase III efficacy trial of nab-paclitaxel (CA-012). Patients (⩾18 years of age) received either nab paclitaxel 260 mg/m^2 or 175 mg/m^2 solvent-based paclitaxel intravenously every 3 weeks for treatment of MBC. Subgroups included patients with or without visceral dominant lesion sites and with ⩾3 or <3 sites of metastases.

	Visceral disease		Nonvisceral disease		⩾3 metastases		<3 metastases	
	Nab-pac (n = 177)	SB-pac (n = 182)	Nab-pac (n = 51)	SB-pac (n = 43)	Nab-pac (n = 141)	SB-pac (n = 117)	Nab-pac (n = 85)	SB-pac (n = 107)
ORR, %*	34	19	34	19	26	17	46	20
P-value	0.002		0.074		0.092		<0.001	
TTP, wks	21.9	16.4	24.4	19.3	19.4	16.3	28.4	16.9
P-value	0.036		0.026		0.053		0.014	

Nab-pac = Nab-paclitaxel; SB-pac = Solvent-based paclitaxel; ORR = Overall response rate; TTP = Time to disease progression.

*Overall response rates for visceral vs nonvisceral disease were reported previously (Gradishar et al. J Clin Oncol. 2005;23:7794–7803).

Conclusions: Patients treated with nab-paclitaxel had superior overall response rates and significantly longer time to disease progression regardless of baseline prognostic factors. Patients with extensive disease had a >20% reduction in the risk of disease progression compared with solvent-based paclitaxel.

Friday, 18 April 2008 12:30–14:30

POSTER SESSION

Predictive and prognostic factors

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The cancer of the male mammary gland in men in Armenia

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Goal: To study the relevance of certain clinical-morphological indicators for the prognosis of the disease.