

## 2082

## POSTER

**Fatigue and depressive symptoms influence quality of life in breast cancer survivors**

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**Background:** Due to early detection since the introduction of breast cancer screening programs and the improvements in treatment, breast cancer has become a chronic disease for many women. Attention for quality of life (QoL) should, therefore, not stop after treatment. To assess the long-term QoL after breast cancer treatment, a cohort study was performed including women who remained disease-free for 5 years after treatment. The outcomes of this study provide an indication for the necessity of psychosocial support after treatment.

**Methods:** Women who were treated for early stage breast cancer between January 2000 and December 2001 were eligible for the study. Exclusion criteria were local recurrence or development of systemic disease, dementia, and no choice between breast conserving therapy (BCT) and mastectomy (MTC) at time of diagnosis.

Out of 251 women, 178 were eligible for participation. They were all contacted by phone and 140 women agreed to participate. They completed questionnaires assessing QoL (WHOQOL-100), depressive symptoms (CES-D), and fatigue (FAS).

**Results:** Overall QoL for breast cancer survivors was comparable with the reported QoL of a healthy reference population. There were no significant differences between the three age-groups (younger than 50 years, 50–70 years, and older than 70 years at time of diagnosis) and the two treatment groups (BCT and MTC) concerning overall QoL and depressive symptoms. Fatigue was positively correlated with age. Regression analyses showed a significant influence of both depressive symptoms and fatigue on overall QoL for both treatment groups and the three age groups.

**Conclusion:** Breast cancer survivors reported an overall QoL that is comparable with the QoL of healthy women. The presence of depressive symptoms and fatigue contributed to an impaired QoL. Age at diagnosis and type of surgical treatment did not influence QoL. Depressive symptoms and fatigue are amenable to psychosocial intervention and this may be worthwhile to improve QoL in patients experiencing depressive symptoms and fatigue.

## 2083

## POSTER

**Adjuvant delivery of a dose-dense, sequential FEC-docetaxel regimen to patients with high-risk breast cancer is feasible – results of a randomized, open-label Phase II study**

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**Methods:** In this prospective, open-label, Phase II study, high-risk primary operable breast cancer patients were recruited at 2 Belgian centres (09/05–07/06). They were randomized (1:1:2:2) to Conventional-A: 3 cycles Q3W FEC (F 500 mg/m<sup>2</sup>, E 100 mg/m<sup>2</sup>, C 500 mg/m<sup>2</sup>) then 3 cycles Q3W Doc 100 mg/m<sup>2</sup>; Conventional-B: reverse sequence (Doc–FEC); dd-C: 4 Q10–11day cycles FEC (E 75 mg/m<sup>2</sup>) then 4 cycles Q2W Doc 75 mg/m<sup>2</sup>; dd-D: reverse sequence (ddDoc–ddFEC). In dd arms, pegfilgrastim was given on Day 2 of each cycle, but was given only as secondary prophylaxis in conventional arms. The primary endpoint was the proportion of patients completing intended cycles at relative dose intensity (RDI) ≥ 85%.

	Conventional		Dose dense	
	A. FEC–Doc (n = 19)	B. Doc–FEC (n = 20)	C. ddFEC–ddDoc (n = 39)	D. ddDoc–ddFEC (n = 39)
Target cycles	100%	95%	97%	92%
FEC target dose	79%	90%	82%	72%
Doc target dose	79%	95%	67%	90%
All CT target dose	74%	85%	67%	72%
RDI ≥ 85%	95%	95%	95%	90%

**Results:** 117 patients were randomized: mean±SD age 48.8±9.1 yrs, 87% ductal carcinoma, 58% stage IIa–b, 4.0±7.0 lymph nodes involved, 72% estrogen receptor positive. In conventional groups (A+B), 31%

received pegfilgrastim secondary prophylaxis. Chemotherapy (CT) delivery is summarized in the table; a high proportion of all groups achieved RDI ≥ 85%. In all, 53%, 25%, 38% and 23%, of groups A, B, C and D had a related grade 3/4 CTC toxicity. Grade 3/4 neutropenia was significantly more frequent in conventional arms (8 [21%] for A+B vs 5 [6%] for C+D; P=0.03), while fatigue and hand–foot syndrome may be more common with dd. Skin toxicity was minimal.

**Conclusions:** Delivery of adjuvant sequential ddFEC–Doc to breast cancer patients is feasible with appropriate growth factor support. Target dose was more easily achieved in the first CT cycles of the dd sequence. There was no clinically relevant increase in toxicity with dd therapy. Further studies are needed to see if this dd regimen confers a survival benefit over conventional delivery.

## 2084

## POSTER

**Acute myeloid leukaemia and myelodysplastic syndrome after taxane-based adjuvant chemotherapy for early breast cancer: an exploratory meta-analysis**

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**Background:** Acute myeloid leukemia (AML) and the myelodysplastic syndrome (MDS) are rare but life-threatening side effects of breast cancer chemotherapy. The taxanes, docetaxel and paclitaxel, have recently emerged as effective agents for the adjuvant treatment of early stage breast cancer. We performed an exploratory meta-analysis to investigate whether the incidence of AML/MDS differs between patients treated with taxane- or anthracycline-based regimens.

**Methods:** We searched the MEDLINE database, the online proceedings of the American Society of Clinical Oncology and the San Antonio Breast Cancer Symposium to identify trials randomizing patients with early stage breast cancer to either taxane- or anthracycline-based chemotherapy regimens after surgery. Trials with treatment arms differing solely regarding the administration of taxane, with doses of all other drugs being identical across treatment arms, were analyzed separately. We abstracted data on AML and MDS incidence. Fixed effects meta-analysis was performed to estimate combined odds ratios (OR) and their confidence intervals, with values higher than one indicating that AML/MDS is more common in patients receiving a taxane. Continuity correction, proportional to the relative size of the opposite of the study, was used for studies with zero events in one arm. Sensitivity analysis was performed using different correction methods or no correction. Results are presented in accordance with the QUOROM guidelines.

**Results:** Out of nine eligible trials (15,960 patients), one did not report on AML/MDS incidence. The eight trials included in this analysis allocated a total of 14,605 patients to docetaxel-based (3,663), paclitaxel-based (3,654) or anthracycline-based (7,288) regimens. 24 cases of AML/MDS occurred in patients who received a taxane and 22 in those who did not. Overall, we found no difference in AML/MDS incidence between taxane- and anthracycline-based regimens (OR, 1.08; 95% CI, 0.59 to 1.96). This held true when trials evaluating docetaxel (OR, 0.93; 95% CI, 0.38 to 2.25) and paclitaxel (OR, 1.22; 95% CI, 0.54 to 2.75) were analyzed separately. Four trials had arms differing solely regarding taxane administration (10,549 patients; 5,259 receiving anthracycline-based and 5,290 receiving taxane-based regimens). Analysis of those trials revealed no correlation between taxane administration and AML/MDS development (OR, 1.24; 95% CI, 0.66 to 2.33). Sensitivity analysis revealed no inconsistencies between different calculation methods.

**Conclusion:** The incidence of AML/MDS following treatment with taxane-based regimens was low. We found no evidence of increased incidence of AML/MDS events in patients receiving taxane-based regimens for early stage breast cancer, when compared to patients receiving anthracycline-based regimens. AML/MDS is a serious consequence of adjuvant chemotherapy, given that treated patients achieve long-term breast-cancer specific survival, and long term surveillance is warranted.

## 2085

## POSTER

**Stage migration in breast cancer: a trend towards better disease free survival for N0 patients since the introduction of the sentinel lymph node (SLN) procedure**

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**Background:** The extensive pathologic examination following introduction of the SLN procedure in breast cancer patients has resulted in the more frequent finding of limited lymph node involvement in breast cancer