Material and Methods: From January, 2008, to December, 2009, 455 patients from 99 participating sites were randomized to lapatinib, trastuzumab or both drugs for 6 weeks (no chemotherapy). After this biological window, patients continued on the same targeted therapy plus weekly paclitaxel for a further 12 weeks until surgery. After surgery, patients received 3 cycles of adjuvant FEC followed by the same anti-HER2 therapy for a further 34 weeks.
FDG PET/CT was performed in a subset of 85 patients at baseline, week 2 and week 6 for early assessment of response to targeted therapies alone without chemotherapy in patients enrolled in 30 qualified sites. Central validation of acquisition parameters and imaging analysis were performed by two blinded reviewers. Description of the lesions includes localization, metabolic volume, SUVmax and SUVmean. Metabolic parameters at week 2 and week 6 will be compared to baseline. Patients will be classified as responders in case of tumour metabolic complete response (mCR) or partial response (mPR) and non-responders in case of metabolic stable disease (mSD). The aim of this analysis is to test whether metabolic response with anti-HER2 therapies alone predicts pCR at the time of surgery.
Results: The last breast surgery was performed in May 2010. FDG PET/CT data cleaning and analysis will be completed by April 2011 and final results on the predictive value of early FDG PET/CT in this large phase III study will be presented at the meeting.
Conclusions: FDG PET/CT data analysis will be discussed at the meeting according to the results obtained.

5014 ORAL

High Risk of Non-sentinel Node Metastases in a Group of Breast Cancer Patients With Micrometastases in the Sentinel Node

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Background: Axillary lymph node dissection (ALND) in breast cancer patients with positive sentinel nodes (SN) is under debate. The aim of this study was to identify a group of breast cancer patients with micrometastases or isolated tumour cells (ITC) in the SN where ALND might still be recommended because of a high risk of non-sentinel node (NSN) metastases. Furthermore, the aim was to identify a group of patients with a minimal risk of NSN metastases, justifying omission of ALND in any case.
Materials and Methods: A total number of 1577 breast cancer patients with micrometastases and 304 patients with ITC in the SN, operated on between 2002–2008 with sentinel lymph node dissection and subsequent ALND, was identified retrospectively using the nationwide Danish Breast Cancer Cooperative Group database. Data was validated using original pathology files and specimens. The risk of NSN metastases was calculated according to clinicopathologic variables in univariate and multivariate logistic regression analyses.
Results: 18% of patients with micrometastases and 9% of patients with ITC had NSN metastases. The risk of NSN metastases in patients with micrometastases was significantly related to tumour size, lymphovascular invasion, hormone receptor status, location of tumour in the breast and proportion of positive SN in the multivariate analysis. A model based on these risk factors identified 5% of patients with a risk of NSN metastases as high as 37%. On the other hand, the model was only able to identify less than 10% of patients with a very low risk of NSN metastases.
The risk of NSN metastases in patients with ITC in the SN was significantly related to age, tumour size and proportion of positive SN in the multivariate analysis. No subgroup of patients with ITC had a risk of NSN metastases over 25%. Patients with tumour size <2 cm and one or more negative SN, corresponding to 34% of patients with ITC, had a very low risk of NSN metastases. Omission of ALND in this group would result in a false negative rate of only 7%.
Conclusions: We have identified a group of patients with micrometastases in the SN with high risk of NSN metastases on nearly 40%, comparable to the risk for patients with macrometastases. ALND may still be recommended in these patients despite new evidence indicating omission of ALND to be safe in selected patients with positive SN. In patients with ITC no subgroup had a risk of NSN metastases over 25%, whereas 1/3 of the patients had a very low risk of NSN metastases, justifying omission of ALND.

5015 ORAL

Age Specific Competing Mortality in Breast Cancer Patients – a TEAM Study Analysis

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Background: In addition to tumour related prognostic factors, characteristics of breast cancer patients may affect outcome. The aim of this study was to assess competing mortality in postmenopausal women with early breast cancer of the TEAM (Tamoxifen Exemestane Adjuvant Multinational) trial.
Material and Methods: 9,766 women were enrolled in the TEAM trial, randomized to either Exemestane 25 mg daily for 5 years or Tamoxifen 20 mg daily for 2.5−3 years, followed by Exemestane 25 mg daily for 2−2.5 years. Five-year results showed no difference in outcome between both arms (*Lancet* 22;377:321, 2011) enabling to analyze causes of mortality in the entire population. Patients were stratified by age at diagnosis (<65, 65−74, ⩾75 years) and survival was calculated by a Cox Proportional Hazard Model (A) as well as a Fine and Gray Model for competing mortality (B).
Results: All patients had hormone receptor positive tumours, 50% had node negative disease, 68% received radiotherapy, and 36% received chemotherapy. After a median follow up of 5.1 years, multivariable analysis using model A showed a higher proportion of breast cancer specific and non breast cancer related mortality with increasing age ($p < 0.001$). Using model B, which takes into account the risk of competing mortality, a higher breast cancer mortality over age was confirmed ($p < 0.001$) (Table 1).
Conclusions: Though the chance of dying from other causes than breast cancer was much higher in elderly patients, breast cancer mortality increased with higher age as well. Additionally, survival analyses evaluating the risk of competing mortality confirmed a higher absolute breast cancer mortality in the elderly, suggesting the possibility of suboptimal treatment. These data underline the need for optimal, individualized treatment of the elderly breast cancer patient, taking into account biological age and life expectancy, in order to improve breast cancer outcome in all age groups.

Table 1. Mortality analyses

	Breast cancer mortality			Non breast cancer mortality		
	5 yrs %	HR* (95% CI)	p value	5 yrs %	HR (95% CI)	p value
Cox Regression			**<0.001**			**<0.001**
<65 years	5	1 (reference)		1	1 (reference)	
65−75 years	6	1.23 (1.09–1.61)		5	2.56 (1.94–3.37)	
⩾75 years	8	1.86 (1.44–2.40)		14	7.08 (5.32–9.41)	
Fine and Gray			**<0.001**			**<0.001**
<65 years	5	1 (reference)		1	1 (reference)	
65−75 years	6	1.22 (1.00–3.26)		5	2.46 (1.86–3.25)	
⩾75 years	8	1.50 (1.16–1.94)		14	6.57 (4.90–8.80)	

*HR (hazard ratios) adjusted for country, histological grade, tumour size, nodal staus, ER, PgR, type of surgery, radiotherapy and chemotherapy.

Poster Discussion Presentations (Mon, 26 Sep, 11:00−12:00)

Breast Cancer

5016 POSTER DISCUSSION

BIG 1-98 Update: Evaluating Letrozole and Tamoxifen Alone and in Sequence at 8 Years Median Follow-up for Postmenopausal Women With Steroid Hormone Receptor-Positive Breast Cancer

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Background: BIG 1-98 is a Phase III randomized, double-blind trial comparing letrozole (Let), tamoxifen (Tam) and sequences of Let and Tam as adjuvant endocrine therapy for postmenopausal women with endocrine-responsive early breast cancer. In 2005 the superiority of Let over Tam for