consevutively or 6 cycles of AD and then complete resection. Each cycle of chemotherapy in this group was performed at the interval of 3 weeks. The group of ACT was scheduled for 4 cycles of AC regimen (50 mg/m^2 and 500 mg/m^2, respectively) and then 4 cycles of paclitaxel(175 mg/m^2) at the interval of 3 week, respectively, before surgery. The patients who were confirmed systemic metastasis at the time of initial diagnosis or within 3 month after surgery and received therapy other than routine scheduled regimen were excluded.

Results: The patients who were enrolled in this study were totally 78 (AD and ACT were identically 38.) The significant differences of patients' characteristics before neoadjuvant chemotherapy were not observed between two groups. However, the significant differences were identified in hematologic toxicity including neutropenia more than grade 3 ($p < 0.001$), neutropenic fever ($p < 0.001$), dose reduction due to hematologic toxicity ($p = 0.012$) and chemotherapy induced anemia ($p = 0.012$), although chemotherapy induced thrombocytopenia ($p = 1.0$) was not different between two gruops. No differences were identified in non-hematologic toxicity including hepatic toxicity [AST ($p = 1.0$), ALT ($P = 0.783$) and bilirubin($p = 1.0$)], gastrointestinal toxicity [nausea, vomiting ($p = 0.529$) and diarrhea ($p = 1.0$)[and peripheral neuropathy ($p = 1.0$). The response of chemotherapy was no difference between two group, which was estimated by conversion rate of breast conserving surgery ($p = 1.0$), clinical response of chemotherapy ($p = 0.148$), clinically downstaging rate ($p = 0.464$) and pathologic complete response rate ($p = 1.0$). There is no factor to predicting pathologic complete response or conversion to breast conservation in this study.

Conclusions: The ACT regimen, compared to AD regimen, has an equivalent response to chemotherapy and a less side effect.

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Recurrence Score (RS) and Treatment Decisions in Node-positive (N+), Estrogen Receptor-positive (ER+) Breast Cancer Patients in Israel

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Background: RS, determined using the Onco*type* DX® assay, has a prognostic utility and can predict response to chemotherapy in node negative ER+ breast cancer patients. We evaluated the relationship between RS and treatment decisions in N+/ER+ breast cancer patients in Israel.

Materials and Methods: Eligible patients had micrometastases (Nmic) or 1−3 positive nodes, ER+ breast cancer and were reimbursed by Clalit Health Services (CHS) for the Onco*type* DX assay between 3/2006 and 11/2009. Claims data were reviewed to identify treatment received (chemotherapy plus hormonal therapy [CHT] vs hormonal therapy alone [HT]).

Table: Proportion of CHT-treated patients by RS, nodal status, and age group

Age group	Low RS (<18)	Intermediate RS (18−30)	High RS (⩾31)
Nmic			
<40 y (n = 3)	0% (0/1)	− (0/0)	100% (2/2)
40−55 y (n = 51)	3.6% (1/28)	26.3% (5/19)	100% (4/4)
>55 y (n = 81)	4.1% (2/49)	28.0% (7/25)	100% (7/7)
Total (n = 35)	3.8% (3/78)	27.3% (12/44)	100% (13/13)
1 positive node			
<40 y (n = 2)	0% (0/1)	100% (1/1)	− (0/0)
40−55 y (n = 27)	26.7% (4/15)	63.6% (7/11)	100% (1/1)
>55 y (n = 72)	7.1% (3/42)	35.7% (10/28)	100% (2/2)
Total (n = 101)	12.1% (7/58)	45% (18/40)	100% (3/3)
2−3 positive nodes			
<40 y (n = 1)	− (0/0)	0% (0/1)	− (0/0)
40−55 y (n = 10)	0% (0/6)	50% (2/4)	− (0/0)
>55 y (n = 35)	7.1% (1/14)	42.1% (8/19)	100% (2/2)
Total (n = 46)	5.0% (1/20)	41.7% (10/24)	100% (2/2)
All patients			
N = 282	7.1% (11/156)	37.0% (40/108)	100% (18/18)

Results: 282 patients were included in the analysis (6 patients <40 y; 88 patients between 40 and 55 y; 188 patients >55 y). Distribution of nodal status and age as well as RS results are shown in the Table. In total, after having the RS, 69 patients (24%) received CHT and 213 patients (76%) received HT. Overall, 7% of patients with low RS, 37% of patients with intermediate RS, and 100% of patients with high RS received CHT. In all examined nodal status groups, the proportion of CHT-treated patients was smaller in the low RS group than in the corresponding intermediate RS group and all patients with high RS received CHT (Table).

Conclusions: The RS seems to impact treatment decisions in N+ (Nmic or 1−3 positive nodes) ER+ breast cancer patients over 55 y in Israel more than nodal status. In younger patients data are limited due to a small sample size.

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Phase II Study of Neoadjuvant Pegylated Liposomal Doxorubicin and Cyclophosphamide +/− Trastuzumab Followed by Docetaxel in Locally Advanced Breast Cancer (LABC)

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Background: The primary end point of this study was the clinical response rate of neoadjuvant pegylated liposomal doxorubicin (Caelyx®) and cyclophosphamide +/− trastuzumab followed by docetaxel in patients with LABC. Secondary end points included determination of the rate of pathological complete response (pCR) and evaluation of the safety of the combination regimen.

Material and Methods: Patients (pts) with inflammatory, locally advanced breast cancer or a tumor >5 cm were enrolled. Pts received 4 cycles of pegylated liposomal doxorubicin 35 mg/m^2 and cyclophosphamide 600 mg/m^2 on q21d followed by 4 cycles docetaxel 100 mg/m^2 q21d. Pts with HER2-positive tumors were concurrently treated with trastuzumab 6 mg/kg q21d for 8 cycles.

Results: From March 2009 to October 2010 49 pts were enrolled. One pt was excluded from the study as she turned out to have sarcoma. Thus, 48 pts were assessable for toxicity. The median age was 50 years (range 31−69). 26 pts. (54%) were premenopausal and 22 (46%) postmenopausal. 14 pts (29%) had tumor T4, 32 (67%) T3 and 2 (4%) T2. 11 pts (23%) had HER2-positive tumor and 7 (15%) had triple negative tumor.

All 8 cycles of neoadjuvant therapy were completed as planned in 40 pts (83%), 6 (13%) discontinued treatment due to toxicity after 5−7 cycles and 2 pts discontinued due to clinical suspicion of progression and patient's wish, respectively. One patient developed an anaphylactic reaction to the first infusion of pegylated liposomal doxorubicin. 47 pts were therefore assessable for response evaluation.

Investigator-assessed clinical response rate was 83%, 3 pts (6%) had a clinical complete response and 36 (77%) had a partial response. One patient was clinically suspected for progression but operation showed response. pCR rate was 19% (9 pts).

The primary toxicity observed was skin toxicity. Palmar-plantar erythrodysesthesia (PPE) grade 3 was observed in 10 pts (21%) and grade 4 in 6 (13%). Other most frequent grade ⩾3 adverse events were: pain (31%), neurotoxicity (21%), fatigue (21%), febrile neutropenia (19%), mucositis (8%). No changes in cardiac function were seen. There were no treatment-related deaths.

Conclusions: The combination of pegylated liposomal doxorubicin and cyclophosphamide +/− trastuzumab followed by docetaxel is highly active in LABC with an acceptable safety profile. The primary toxicity was cutaneous toxicity which was manageable.

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Genetic Variability in the Methylenetetrahydrofolate Reductase (NAD(P)H) Gene (MTHFR) is Associated with Severe Non Hematological Toxicity of Adjuvant FEC in Breast Cancer

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Background: We assessed the impact on non hematological chemotherapy toxicity of single nucleotide polymorphisms (SNP) in germline DNA in a panel of potential genes of interest through high throughput sequencing. First aim was to validate the predictive value of certain SNP