**Results:** 64 patients (23.7%) experienced a pCR. Univariate logistic regression revealed estrogen receptor (ER) negativity, progesterone receptor (PR) negativity, Human Epidermal Growth Factor receptor 2 (HER2) positivity, high histologic tumor grade, high clinical lymph node stage and non-lobular type as significant predictors for pCR ($p < 0.05$). Age at diagnosis beyond 60 and tumor size had a marginally positive effect; $p = 0.070$ for age and $p = 0.106$ for tumor size. A multivariate analysis taking these variables into consideration showed that ER (odds ratio=0.218, 95% CI 0.111–0.429, $p < 0.001$), HER2 (odds ratio=3.766, 95% CI 1.967–7.209, $p < 0.001$) and the clinical lymph node stage (odds ratio=1.481, 95% CI 1.035–2.119, $p = 0.032$) were the only independent predictors for pCR (see Table).

**Conclusions:** Our study including 270 consecutive patients diagnosed with large size of locally advanced breast cancer showed that ER, HER2 and the clinical lymph node stage are predictive of pCR.

Table: Multivariate model

| Parameters | Estimate | SE | Wald $\chi^2$ | Odds ratio | 95% CI | p-value |
|---|---|---|---|---|---|---|
| Intercept | −1.5236 | 0.3742 | 16.5820 | | | <0.0001 |
| ER | −1.5237 | 0.3451 | 19.4950 | 0.218 | 0.111–0.429 | <0.0001 |
| HER2 | 1.3260 | 0.3313 | 16.0187 | 3.766 | 1.967–7.209 | <0.0001 |
| Clinical LN stage | 0.3928 | 0.1828 | 4.6193 | 1.481 | 1.035–2.119 | 0.0316 |

**30** Poster

**Outcome in patients with hormonal receptor positive inflammatory breast cancer substantially improved with adjuvant hormonal therapy**

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**Background:** Inflammatory breast cancer (IBC) is characterized by extensive lymphovascular invasion, nodal involvement and poor clinical outcome. The aim of our study was to evaluate the role of adjuvant hormonal therapy on outcome of hormone receptor positive (HR+) IBC.

**Material and Methods:** We retrospectively evaluated the outcome of two series of IBC patients treated at the Institute of Oncology Ljubljana, Slovenia, in years 1983−87 (series A) and 2001−05 (series B). Patients without distant metastatic disease were included (59 patients in each of series).

**Results:** Patients were aged 28−74 (median 54) and 34−83 (median 56) years in series A and B, resp. Axillary lymph nodes were involved in 54/58 and 38/50 pts undergoing induction chemotherapy, mastectomy and axillary dissection (series A and B, resp.). Hormonal receptors were positive in 27/50 (9 unknown) and 31/58 (1 unknown) of pts (series A and B, resp.). HER2 status was determined only in series B (22/52 HER2+, 7 unknown). All pts in series A were treated with CMF chemotherapy, whereas pts in series B were treated with anthracyclines alone (56%), combination of anthracyclines and taxanes (36%) or CMF chemotherapy (7%). In series A 7/27 HR+ pts received adjuvant hormonal therapy (tamoxifen, mean duration 18 months). In series B 28/31 HR+ pts received adjuvant hormonal therapy (mean duration 39 months; 7 received tamoxifen, 12 aromatase inhibitors, 9 switched from tamoxifen to aromatase inhibitors). Adjuvant trastuzumab was applied in 7/22 HER2+ pts. Adjuvant radiation therapy received 73 and 81% of pts (series A and B, resp.). Median relapse-free (RFS) and overall (OS) survival was 16.9 vs. 34.2 months ($p = 0.01$) and 33.8 vs. 56.6 months ($p = 0.06$); series A vs. B, resp. Improved RFS in series B is probably due to more potent chemotherapy (anthracyclines and taxanes vs. CMF), trastuzumab and hormonal therapy. In patients with HR+ IBC RFS was 75.4 vs. 16.5 months (series B vs. A, resp.), probably due to adjuvant hormonal therapy. In series B median RFS in HR+ IBC according to type of hormonal therapy was: 25 vs. 34.9 months vs. not reached (tamoxifen vs. aromatase inhibitors vs. switch; $p = 0.015$) and only 15 months in HR− IBC.

**Conclusions:** Patients with HR+ IBC seems to benefit substantially from adjuvant hormonal therapy. Of them switching strategy (from tamoxifen to aromatase inhibitors) seems to be the most effective. Prospective randomised trials addressing this issue are warranted.

**31** Poster

**Endometrial cancer after breast cancer and relationship with tamoxifen**

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**Background:** Breast cancer and endometrial cancer are frequently diagnosed in the same patient. Tamoxifen use in breast cancer patients may increase endometrial cancer incidence. The purpose of the study was to analyze endometrial cancer with breast cancer history characteristics and prognosis, and whether or not the use of tamoxifen influences the prognosis of endometrial cancer.

**Materials and Methods:** A retrospective study has been conducted in patients with endometrial cancer in a single institution with 3 groups according to breast cancer history: breast cancer history with tamoxifen use; breast cancer history without tamoxifen use, no history of breast cancer. Diagnosis modalities, histologic characteristics, FIGO status, and survivals were studied.

**Results:** From 1994 to 2004, 401 patients had been referred to Institut Curie for an endometrial cancer and 363 were eligible for the study: 80 (22%) of patients had a previous diagnosis of breast cancer history. Among them, 43 patients had tamoxifen (group 1) and 37 did not (group 2). The median duration of tamoxifen use was 48 months [4–108]. In the group 3 (no history of breast cancer), there were 283 patients.

Systematic pelvic ultrasound diagnosis was more frequent in tamoxifen group (14% vs 5 and 4%) $p = 0.02$. Carcinosarcoma histologic type was more frequent in tamoxifen group (11.7% vs 5.4% and 4.2%) $p = 0.1$. Well differentiated tumors were less frequent in tamoxifen group (42.5% vs 55.5% vs 61.7%) $p = 0.08$. No difference was noted in FIGO status. The 5-year OS was poorer in Tamoxifen group than in the 2 other groups (respectively 61.3% vs 73.25 vs 82%); $p = 0.0006$. Prognostic factors for endometrial cancer associated with OS in the multivariate analyzis were age at diagnosis, FIGO status and tamoxifen use (RR = 3.83 [1.68–4.77]; $p < 0.001$). The 5-year Local Relapse Free Survival was poorer in Tamoxifen group 82.55 vs 93.1% vs 95.9% ($p = 0.02$).

**Conclusion:** In this study, breast cancer history with tamoxifen use appears as a poor pronostic factor in endometrial cancer suggesting a tamoxifen role in endometrial cancer agressivity.

**32** Poster

**ASTRRA study: a randomised phase III study for evaluating the role of the addition of ovarian function suppression (OFS) to tamoxifen in young women (<45 years) with hormone-sensitive breast cancer who remain in premenopause or regain menstruation after chemotherapy − a Korean Breast Cancer Study Group (KBCSG) trial**

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**Background:** About 60% of newly diagnosed breast cancer patients are premenopausal in Korea and it is already known that these young women have worse prognosis compared to postmenopausal patients. Tamoxifen resistance may contribute to the poor prognosis in this group, however the clinical role of adding OFS for young women who remain premenopausal or resume menstruation after chemotherapy is still controversial. There are several ongoing trials such as SOFT, TEXT, PERCHE, but in these trials, the menopausal status was assessed only one time after chemotherapy. The ASTRRA study is aimed to answer 2 main questions. One is, if the addition of OFS to an adjuvant chemotherapy plus tamoxifen in young women with ER+ tumour who remain premenopausal will provide benefit and the other is, if the delayed OFS followed the monitoring of the menopausal status until 2 years after an adjuvant chemotherapy will be beneficial in terms of disease-free survival (DFS).

**Material and Methods:** The ASTRRA study is a multi-center, open-labelled, randomized, phase III study targeting 1234 patients from 36 centers in Korea and first subjects in (FSI) was in April, 2009. The ASTRRA study has been designed to compare DFS between the OFS + tamoxifen group and tamoxifen only group in premenopausal breast cancer patients. All the patients will be premenopausal prior to chemotherapy, less than or equal to 45 years of age with estrogen receptor positive (ER+ve) who have undergone a surgery for primay tumor, received an adjuvant chemotherapy±radiotherapy for their stage I, II or III breast cancer. At 0, 6, 12, 18 and 24 months since the baseline assessment, the ovarian function status will be evaluated by menstruation status or serum FSH level. If the patients are regarded as premenopausal, they will be randomized into the OFS + tamoxifen group or tamoxifen only group. All the patients who were eligible at the baseline for further follow-up will be followed up until 5 years for assessing primary and secondary objectives. All the patients will complete taking tamoxifen 20 mg/day for 5 years if they remain in the study. OFS will be done by administration of goserelin for 2 years.

**Results:** The main study endpoints are 5 year DFS rate, overall survival, and the tolerability of goserelin and tamoxifen. This study is now enrolling patients (208/1234) with good recruitment rate.

**Conclusions:** This study is expected to complete recruitment April 2011 and there could be an interim-analysis of the study after recruitment completion. The ASTRRA study is one of the largest study evaluating the role of OFS after chemotherapy and the study would be able to answer some important questions which is still controversial.

**33** Poster

**Comparison of sonographic and pathologic measurements of breast tumour size after preoperative chemotherapy based on intrinsic subtypes**

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**Background:** Breast ultrasonography (US) is used for measurement of the size of breast tumors due to its ease of use, simplicity and low invasiveness. However, tumor size measured by US often differs from that determined pathologically after preoperative chemotherapy, and this can make it difficult to determine the required extent of resection in breast-conserving surgery (BSC). Therefore, we examined whether the difference between sonographic and pathologic measurements could be reduced by consideration of intrinsic subtypes.

**Material and Methods:** 140 breast tumors underwent neoadjuvant treatment for Stage II-III breast cancer between 2003 and 2008 were classified into four subtypes based on ER, PgR and HER2 expression determined by immunohistochemistry. These were defined as the luminal A, luminal B, HER2 and triple negative (TN) subtypes. Tumors with a difference of ±1 cm between the long axis measured by US and pathologically were classified as correctly estimated by US. Tumors for which the US diameter was shorter than the pathologic diameter by more than 1 cm were considered to be underestimated by US, and those that were longer than the pathologic diameter by more than 1 cm were considered to be overestimated by US. The rates for correct, under and overestimation and the margin-positive rate in BCS (tumor resected with a 2-cm margin) were determined for each subtype.

**Results:** The rates of correct, under and overestimation of the tumor size in all patients were 69%, 20% and 11%, respectively. For the luminal A, underestimation occurred in 30% of cases, but overestimation in only 3%. In contrast, the sizes of the HER2 and TN were underestimated in 0% and 4% of cases, but overestimated in 28% and 19%, respectively (Table 1). These data differed significantly in each group ($P < 0.01$). BCS was performed in 97 cases and the margin was positive in 20 of these cases (21%). The margin-positive rate for the luminal A was significantly higher than those for the other three subtypes ($P = 0.04$).

Table 1

| Estimate | Subtype | | | |
|---|---|---|---|---|
| | Luminal A | Luminal B | HER2 | TN |
| Under estimate | 22 (30%) | 5 (22%) | 0 (0%) | 1 (4%) |
| Correct estimate | 49 (67%) | 14 (61%) | 13 (72%) | 20 (77%) |
| Over estimate | 2 (3%) | 4 (17%) | 5 (28%) | 5 (19%) |

**Conclusions:** A comparison of sonographic and pathologic measurements of breast tumor size after preoperative chemotherapy was performed based on intrinsic subtypes. The tumor size for the luminal A tended to be underestimated before BCS, whereas the sizes of the HER2 and TN tended to be overestimated. These findings indicate that the subtype should be considered in determination of the surgical resection range using diagnostic ultrasound after preoperative chemotherapy.

**34** Poster

**Comparison of 6 cycles versus 4 cycles of neoadjuvant epirubicin plus docetaxelchemotherapy in stages II and III breast cancer**

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**Background:** This phase III clinical study was designed to investigate whether 6 cycles of epirubicin plus docetaxel (ED) is more effective than 4 cycles of ED as neoadjuvant chemotherapy (NC) in patients with stage II or III breast cancer.

**Patients and Methods:** Women with breast cancer that had tumors larger than 3 cm were prospectively randomized to receive 4 or 6 cycles of epirubicin 75 mg/m$^2$ and docetaxel 75 mg/m$^2$ every 3 weeks. The primary end point was the clinical response to NC.

**Results:** A total of 176 patients were randomly assigned, and 150 patients were assessable for efficacy and toxicity. Groups were well balanced for clinicopathologic parameters. The median age was 42 years (range 30−58). Overall clinical response was observed in 72% with ED4 and 82% with ED6. pCR was observed in 11% with ED4 and in 24% with ED6 ($p = 0.047$). 47% of the ED4 group underwent breast conserving surgery (BCS) whereas 58% of ED6 group underwent BCS. Grade 3/4 neutropenia was observed in 27% in ED4 and 31% in ED6. Febrile neutropenia occurred in 17% with ED4 and 19% with ED6. Grade 3 mucositis was observed in 8% with ED4 and in 6% with ED6.

**Conclusion:** Six cycles of ED enhanced the rates of pCR and BCS compared with 4 cycles without increasing treatment-related toxicities.

**35** Poster

**High pathologic complete remission rate with liposome-encapsulated doxorubicin + paclitaxel + trastuzumab as primary treatment in HER-2 positive operable breast cancer: clinical experience**

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**Background:** The combination of liposome-encapsulated doxorubicin + paclitaxel + trastuzumab is associated with high response rate without risk of clinical congestive heart failure. We present our clinical experience with this combination as primary treatment in HER-2 positive operable breast cancer, describing efficacy and toxicity data.

**Material and Methods:** Twenty patients with previously untreated HER-2 positive were analysed. Primary treatment consisted of 6 cycles of liposome-encapsulated doxorubicin (50 mg/m$^2$ 3-weekly), paclitaxel (80 mg/m$^2$/week) and trastuzumab (4 mg/kg loading dose, then 2 mg/kg/week). Tumor response was evaluated with imaging studies after the third cycle and before the surgery. Cardiac evaluation was performed at baseline and repeated after completion of the primary treatment. All patients underwent surgery. Pathologic complete response (pCR) was defined as complete disappearance of all invasive cancer in breast and axilla.

**Results:** Between August 2008 and October 2009 twenty patients (5 stage IIb, 13 stage IIIa, 3 stage IIIb) completed primary treatment. Median age 47.36 (range 33.4–61.4). All patients achieved clinical response: 11 CR (55%) and 9 PR (45%). 6 patients underwent conservative surgery (33.3%). 14 patients achieved pCR (70%) and in 3 patients rested minimal residual disease (<0.5 cm) (15%). By status hormone receptor (HR) pCR was 4/6 (66.6%) in HR positive and 10/12 (83.3%) in HR negative. All 6 planned cycles of treatment was completed by 17 patients (85%). In terms of toxicity 4 patients had presented one episode of neutropenic fever (20%); none of these patients presented new episodes of neutropenia after the administration of prophylactic granulocyte colony-stimulating factor. Any patient developed congestive heart failure, a decrease between 10−20% in the cardiac ejection fraction, asymptomatic and above normal limit was observed in 5 patients (25%).