

**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 primary 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 (BCS). 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  $\pm 1$  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 docetaxel chemotherapy 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<sup>2</sup> and docetaxel 75 mg/m<sup>2</sup> 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<sup>2</sup> 3-weekly), paclitaxel (80 mg/m<sup>2</sup>/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%).