of tumor grade. If PgR negative, A-CMF CHT was given, while in a case of PgR positive disease, adjuvant endocrine therapy was introduced. A group of patients with SR-positive tumors defined as ER-positive/PgR-positive, ER-positive/PgR-negative, and ER-negative/PgR-positive were separated and divided according to menopausal status. Among these premenopausal (N = 196) and postmenopausal (N = 193) women disease-free survival (DFS) and overall survival (OS) were compared between women treated with A-CMF CHT and adjuvant endocrine therapy.

Results: Significantly more premenopausal patients treated with A-CMF CHT had grade 3, PgR negative breast tumors (Chi-square tests $p = 0.049$, $p < 0.001$ respectively), while significantly more women treated with OA had positive lymph nodes (Chi-square test, $p = 0.007$). In postmenopausal groups, significantly more women treated with A-CMF CHT had lower PgR (Chi-square test, $p < 0.001$), node negative status (Chi-square test, $p = 0.003$) and less frequently received postoperative radiotherapy (Chi-square test, $p < 0.001$) compared to postmenopausal patients treated with adjuvant TAM. There was no difference in DFS and OS between premenopausal women treated with A-CMF CHT and those treated with OA. However, significantly more postmenopausal patients, treated with A-CMF CHT, developed disease relapse comparing to postmenopausal women treated with adjuvant TAM (Chi-square test, $p < 0.001$), with local recurrences and bone metastases occurring significantly more frequently (Chi square tests, $p = 0.01$, $p = 0.006$, respectively). Furthermore, postmenopausal women treated with A-CMF CHT had significantly worse DFS (Log rank test, $p = 0.013$) compared to TAM group, while there was no difference in OS between the two groups.

Conclusion: Our results showed that SR might have some value as a predictive factor for the response to A-CMF CHT at least in postmenopausal women with SR-positive breast cancers.

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Prospective phase II study of: neo-adjuvant doxorubicin followed sequentially by cisplatin/docetaxel in locally advanced breast cancer

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Background: Neoadjuvant (primary) chemotherapy as part of multimodality treatment is increasingly used as standard of care for patients (pts) with locally advanced breast cancer.

We conducted a prospective study using Doxorubicin 75 mg/m^2 q 3 weeks × 3 cycles followed sequentially by Docetaxel 75 mg/m^2 and Cisplatin 75 mg/m^2 q 3 weeks × 3 cycles. All pts had definitive surgery followed by Radiation therapy, +/− Tamoxifen. Primary end points were pathologic complete response (pCR), secondary endpoints were, safety, rate of conservative surgery and overall survival.

Material: Eligible pts included biopsy proven invasive breast cancer, T2-T4 (primary ⩾4−10 cm) N0-N2, M0. 59 of 60 enrolled pts completed treatment one patient refused surgery after the completion of 6 cycles of chemotherapy were excluded from the analysis, Premenopausal: 68%, median age: 41 yrs (24−60), median tumor size: 6.0 cm (4−10), Stage IIB: 31% and IIIA/IIIB: 68%, both ER/PR positive: 53%, Her2/neu (3+) by IHC staining: 29%, Her2/neu (+2) equivocal: 20% were all are FISH negative. All patients had negative metastatic workup.

Results: 59 pts are evaluable for analysis: clinical complete response was seen in: 44%, clinical partial response in: 56%. Breast conserving surgery was performed in: 44%, and MRM in: 56%. Pathological complete response (pCR) in the breast was: 31%, in axilla were: 37%, breast and axilla were 22%.

Grade 3−4 Toxicities: febrile Neutropenia (13%), nausea−vomiting (12%), mucositis (10%), weakness/asthenia/weight loss (12%). Overall at follow up of 50 months the DFS & OS (62% and 87%).Patients who achieved complete pathologic response both in breast and axilla the DFS and OS were (100%).

Conclusion: Sequential combination of Doxorubicin followed by Docetaxel/Cisplatin is a safe, feasible and active combination, that offer the possibility of conservative surgery and associated with high clinical and pathologic response, further investigation of this combinations are warranted.

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Improving breast cancer survival – trends in node negative and node positive disease

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Aim: To determine any improvement in recurrence and survival in node negative and node positive breast cancer patients between 1988 and 1999.

Methods: The study was a retrospective database review of 890 breast cancer patients diagnosed between 1988 and 1999. Patients were divided into 2 groups according to the year of diagnosis (group I: 1988–1994; group II: 1995–1999). Recurrence free survival (RFS), breast cancer specific survival (BCSS) and overall survival (OS) was calculated by Kaplan-Meier life table analysis and compared using the log rank test with both groups stratified for lymph node status.

Results: There were 404 patients in group I and 486 patients in group II. 273 patients in group I and 320 patients in group II were node negative.

5-year RFS in node negative patients was 84% in group I versus 87% in group II ($p = 0.20$), BCSS was 92% in both groups ($p = 0.89$) and OS was 85% in both groups ($p = 0.95$). In node positive patients the 5-year RFS was 57% in group I and 69% in group II ($p = 0.01$), BCSS was 70% versus 78% ($p = 0.047$) and OS was 67% versus 73% ($p = 0.10$).

The use of systemic adjuvant therapy was significantly increased in group II, for node negative (chemotherapy 6% versus 18%, $p < 0.001$; endocrine therapy 74% versus 90%, $p < 0.001$) and for node positive patients (chemotherapy 33% versus 55%, $p < 0.001$; endocrine therapy 81% versus 92%, $p = 0.004$)

Conclusion: The increased use of systemic adjuvant therapy in node negative and node positive breast cancer patients between 1995 and 1999 was reflected in a significant improvement in RFS and BCSS in patients with node positive disease. Patients with node negative disease did not demonstrate any significant differences in recurrence or survival.

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Neoadjuvant capecitabine (X), docetaxel (T) ± trastuzumab (H) for patients (pts) with locally advanced breast cancer (LABC): preliminary safety and efficacy data from a multicentre phase II study

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Background: 3-weekly XT is highly active in metastatic breast cancer, with significantly superior response rates, time to progression and overall survival vs. T alone. X and T are synergistic with H in HER2-positive tumours. We evaluated the efficacy and safety of XT±H as neoadjuvant therapy for LABC.

Materials and Methods: Pts with newly diagnosed invasive stage III inoperable LABC (cT4 and/or cN2−3) received X (900 mg/m^2 orally bid d1−14) + T (36 mg/m^2 i.v. d1&8) q3w x6, followed by surgery and radiotherapy. Pts with HER2-positive tumours (IHC 3+ or FISH+) also received H (8 mg/kg on d1 of the first 3w cycle and 6 mg/kg on d1 of subsequent cycles). Safety was evaluated after each cycle, clinical response after 3 and 6 cycles, and pathological complete response (pCR) postoperatively. pCR was defined as no residual invasive tumour in breast and axilla.

Results: To date, 30/51 pts have completed neoadjuvant chemotherapy (26 pts XT, 4 pts XT+H) and surgery. Baseline characteristics are: median age 50 years (range 25−74), median ECOG PS 0 (range 0−1), ER/PR/HER2+ status 74/61/16%. The most frequent grade 3/4 treatment-related toxicities were diarrhoea (16%), HFS (10%) and stomatitis (10%). Dose reductions were applied because of grade 2−4 adverse events (stomatitis, HFS, diarrhoea, vomiting, peripheral neuropathy and skin rash) in 11 pts and because of neutropenic fever in 2 pts. Therapy was prematurely interrupted because of disease progression (1 pt), capillary leak syndrome (1 pt), infection (1 pt), fever of unknown origin (1 pt) and psychological intolerance (1 pt). The overall response rate was 90%, including 2 CRs (7%) and 25 PRs (83%). A further 2 pts had stable disease (7%). pCR was achieved in 2 pts who completed 6 cycles of XT (8%) and in 2/4 pts (50%) after 6 cycles of XT+H. Most pts received postoperative anthracycline-based chemotherapy (4−6 cycles of