

(median 8, range 1–8). All 8 cycles were completed by 72.4% of pts (15 pts were still on treatment). Median relative dose-intensity of C was 89.9%. The most common grade 3/4 clinical AEs related to C were: hand-foot syndrome (Grade 3 18.6%), diarrhoea (3.5%), fatigue (2.8%), irregular menses (2.4%), neutropenia (1.9%), nausea (0.9%), vomiting (0.7%), bilirubin elevation (0.7%), sensory neuropathy (0.7%) and nail changes (0.5%).

Conclusions: The safety profile of adjuvant C as maintenance therapy is consistent with its known toxicity profile. This analysis will be updated at the meeting with safety data from all randomised pts (876).

	Arm A, C (n = 435)	Arm B, Observation (n = 418)
Median age, years	50	49
KPS, %		
80	1.8	4.1
90	12.9	15.8
100	85.3	80.1
Node-positive (post-surgery), %	45.2	43.0
Basal phenotype, %	72.0	72.7
Histology, %		
ductal	88.1	86.8
lobular	1.8	2.2
other	10.1	11.0
Median tumor size, cm (range)	2.7 (0.8–11.0)	2.7 (0.5–14.0)
Post-menopausal, %	70.1	67.0
Prior standard chemotherapy, %		
Anthracyclines without taxanes	32.1	31.8
Anthracyclines and taxanes	67.9	68.2

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Can Surgery Be Avoided in Patients with Breast Cancer Who Achieve a Complete Clinical Response to Neoadjuvant Chemotherapy?

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Background: The objective of this study was to evaluate the local recurrence rates in patients with primary breast cancer who achieved a complete clinical response (cCR) to neoadjuvant chemotherapy and did not have surgery.

Materials and Methods: 148 women who achieved a cCR to neoadjuvant chemotherapy were identified from a prospectively maintained database (1995–2011) of 667 patients. 122 patients went on to have surgery (either wide local excision or mastectomy) followed by radiotherapy. 26 patients (median age 49, range 35–72 years; T2–T4, N0–N3, M0) did not undergo surgery but instead received radical external beam radiotherapy. Surgery was avoided due to either physician or patient choice. Recurrence was defined as first relapse of disease, either local (ipsilateral breast and/or axilla) or distant.

Results: All 26 patients who did not have surgery received neoadjuvant chemotherapy with 20 patients (77%) receiving anthracycline-based (FEC, FAC, ECF), 5 (19%) MMM and 1 (4%) CMF chemotherapy. The median number of cycles was 6 (range 4–8). Chemotherapy was followed by radical external beam radiotherapy to the breast +/- supraclavicular fossa and axilla (median dose delivered, 60 Gy in 2 Gy fractions). All were identified as operable at diagnosis including 3 patients who had supraclavicular lymphadenopathy. All 26 patients achieved a final cCR in the breast to chemotherapy. 21 patients had imaging with mammography and/or ultrasonography to assess radiological response at the end of neoadjuvant chemotherapy, of which 19 had a complete response and 2, a partial response. After a median follow-up of 144 months, 10/26 (39%) patients experienced local disease recurrence (2 also had distant recurrence) and 4/26 (15%) patients with distant metastases only. Patients with local recurrence only, went on to have a mastectomy whilst those with distant disease received systemic therapy. There were 10 deaths, 9 of which were breast cancer related (35%).

Conclusions: In patients achieving a cCR following neoadjuvant chemotherapy and who avoided surgery, local recurrence rates were high. As a result, practice in our institution has changed to include insertion of clips and surgical excision on completion of chemotherapy. With increasing pathological complete response rates to more active chemotherapy schedules (including taxanes +/- trastuzumab), it has been proposed that surgery could potentially be avoided in certain patients. However, our results demonstrate that caution should be exercised.

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The Role of Cyclin D1 in Planning of Endocrine Therapy for Women of Postmenopausal Age with Breast Cancer

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Background: Nowadays tamoxifen still remains the primary drug in breast cancer endocrine therapy. However, its application is limited due to the resistance of tumor cells. The search of adequate biomarkers is one of the most actual problems in prognosis of effectiveness of tamoxifen adjuvant therapy. The most perspective biomarker is cell cycle regulator cyclin D1. The objective of our work was to evaluate the effectiveness of tamoxifen in adjuvant therapy of hormone-receptor-positive breast cancer in women of postmenopausal age with cyclin D1 expression and to compare the effectiveness of tamoxifen and anastrozole in adjuvant therapy of hormone-receptor-positive breast cancer in women with cyclin D1 expression more than 30%.

Material and Methods: To evaluate the effectiveness of tamoxifen we have researched 2 retrospective groups of 70 patients with hormone-receptor-positive T1–4N0–3M0 breast cancer that have been on regular medical check-up for a period of 5 years or that had previously undergone treatment. On the basis of the archive histological material we have revealed cyclin D1 in tumor cells. To compare the effectiveness of tamoxifen and anastrozole we have additionally researched 1 additional group of 50 patients with breast cancer and cyclin D1 expression more than 30% that have been on regular anastrozole treatment for a period of 27 months.

Results: Patients with lack of cyclin D1 expression or with low quantitative value (according to our data less than 30%) have no neoplastic process progression throughout the 5 years of tamoxifen adjuvant therapy. On the contrary, women with moderate and high cyclin D1 expression (more than 30%) had a relapse of tumor. Thus, distant metastasis is prognosed in 5 years of observation in this patient's group. Moderate level of cyclin D1 expression was observed in 45 (64%) patients and 28 (62%) of them had progression with metastasis in bones, 9 (20%) metastasis in soft tissues, 2 (4%) metastasis in lungs and 6 (14%) relapse in postoperative scar. High expression was revealed in 25 (35%) women and 17 (68%) of them had bone affection, 7 (28%) soft tissue metastasis and 2 (4%) tumor relapse in postoperative scar. The average period of tumor relapse and progression of neoplastic process in patients with cyclin D1-positive breast cancer is 20 months. Patients who have cyclin expression more than 30% and receive anastrozole in adjuvant have no tumor relapse and progression throughout 27 months of observation.

Conclusion: Women with hormone-receptor-positive cyclin D1-negative breast cancer on early stages have more prolonged non-relapse period during the tamoxifen adjuvant therapy. Patients with cyclin D1-positive breast cancer are less sensitive to tamoxifen treatment and in adjuvant regime should receive therapy with other effective equivalent drugs (aromatase inhibitors). It is necessary to continue the research of cyclin D1 as biomarker that could influence on the choice of treatment between tamoxifen and aromatase inhibitors.

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Prognostic Factors for Triple Negative Breast Cancer Patients with Preoperative Systemic Chemotherapy

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Background: Triple negative breast cancer (TNBC), which is immunohistochemically characterized by lack of expression of the estrogen receptor (ER), progesterone receptor (PgR), and HER2, tends to show visceral metastasis and aggressive clinical behavior. The aim of this study is to identify the prognostic factors for patients with TNBC after receiving preoperative systemic chemotherapy (PST).

Materials and Methods: Among 4195 operable primary breast cancer patients, 135 TNBC patients who underwent preoperative systemic therapy between 2000 and 2009 were investigated. The significant prognostic factors among clinicopathological characteristics including familial history, menopausal status, body mass index (BMI), UICC staging before PST, chemotherapy regimen, completion of scheduled chemotherapy, clinical response, surgical procedure, radiotherapy, histological grades, pathological invasive size, pathological nodal status, lymphatic invasion, vascular invasion, HER2 status (0 or 1), pathological complete remission,