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A Phase II study of neoadjuvant chemotherapy (NC) with taxotere, adriamycin and cyclophosphamide (TAC) in locally advanced breast cancer (LABC)

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Background: NC is the standard treatment for LABC. The objective of this study is to determine the response rates and the rates of breast conservation therapy with NC containing TAC in LABC.

Methods: Women were eligible if they were; histological confirmed invasive infiltrating carcinoma, LABC as per AJCC. PS 0–1 with adequate renal, liver and hematological functions. Patients were treated with T (75 mg/m²), A (50 mg/m²) and C (500 mg/m²) 3 to 6 cycles. Followed by surgery and pathological assessment. The post-surgical treatment cycles of TAC regimen and radiotherapy is given on the basis of staging. Tamoxifen was given if they were found hormonal receptors positive.

Results: We have accrued 60 patients with mean age 46 years; 45% were premenopausal; 55% had T3, 25% had T4, while 20% had inflammatory breast cancer. Seventy percent had clinically/mammographically positive axillary lymphadenopathy. Hormonal receptors were positive in 53%. The overall response rate in all 60 pts was 93% with complete pathological response (pCR) in 28.3% and partial response (PR) in 65%. Disease progression was seen in one patient. Grades III–IV toxicities were: neutropenic fever 35%; mucositis 45%, and nausea & vomiting 10%. All patients were operated, 65% had a modified radical mastectomy and 35% had BCT.

Conclusions: Neoadjuvant chemotherapy containing Taxotere, Adriamycin and Cyclophosphamide achieved significant pathological complete response and breast conservation therapy in patients with locally advanced breast cancer.

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Efficiency of Toremifene and Letrozole in the treatment of patients with advanced breast cancer

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Background: For the last years the discussion and researches about efficiency and sequence of use of antiestrogens and aromatase inhibitors in the treatment of advanced breast cancer have not been stopping. For many years antiestrogens (Tamoxifene and Toremifene) were considered standard medicines of first line in the treatment of postmenopausal women with advanced breast cancer. Last years results of researches which have demonstrated advantages aromatase inhibitor Letrozole over Tamoxifene as first line therapy at the patients with advanced breast cancer were published. At the same time did not investigate comparative efficiency high doses of Toremifene and Letrozole. The aim of this trial is comparative study of Toremifene and Letrozole efficiency in the treatment of patients with advanced breast cancer.

Material and methods: 451 receptor statuses not considered patients with advanced breast cancer were involved in this clinical trial. Patient were divided on 4 groups/Hormonal therapy with Tamoxifene at a dose of 20 mg once daily was administered in 117 patients – group I, hormonal therapy with Toremifene at a dose of 60 mg once daily was administered in 115 patients – group II, 106 patients (group III) received Toremifene at a dose of 240 mg daily, 113 patients (group IV) were treated with Letrozole at a dose of 2.5 mg once daily. Patients continued on study medication until disease progression. Efficiency of treatment was determined with following criteria: objective effect, side effects and duration of remission.

Results: In the first group 30(25.6%) patients, in second group 38 (33.0%) patients, in the third group 44 (41.5%) patients, in the fourth group 40 (35.4%) had objective effect. Median remission time of 9.2; 11.3; 14.5 and 13.1 months. Side effects in all groups were not significant, did not require specific correction and delay of the treatment.

Conclusions: Our data indicated about advantages of Toremifene compared to Tamoxifene and comparable efficiency compared to Letrozole. On the base of the data we can recommend Toremifene for wide use as first line hormone therapy of patients with advanced breast cancer.

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Comparison of epirubicin and vinorelbine with cyclophosphamide, epirubicin, and fluorouracil as neoadjuvant chemotherapy for operable breast cancer

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Reasonable activity and favorable safety of vinorelbine in metastatic breast cancer prompt the integration of these agents into the adjuvant

setting. We performed this study to validate the use of vinorelbine as a neoadjuvant therapy in operable breast cancer. The response rates and toxicity profiles of epirubicin plus vinorelbine (EN) were compared with cyclophosphamide, epirubicin, and fluorouracil (CEF) neoadjuvant chemotherapy for operable breast cancer. Eligible criteria for the study was T2 and T3 histologically proven invasive breast cancer without prior systemic treatment and systemic metastasis.

Forty-six patients underwent 4 cycles of EN (epirubicin 75 mg/m², vinorelbine 30 mg/m²) every 3 weeks and 38 patients underwent 4 cycles of CEF (cyclophosphamide 600 mg/m², epirubicin 75 mg/m², fluorouracil 600 mg/m²) every 3 weeks. All the patients underwent curative surgery 3 weeks after the completion of 4 cycles of neoadjuvant chemotherapy. Response rates, which were evaluated by pathologic examination after curative surgery, and adverse effects were analyzed at the admission for operation. Median age and tumor size were well matched between 2 groups (median age: EN 42 yr; CEF 45 yr, median size: EN 5 cm; CEF 5 cm). Response rate was 63% (CR: 4, PR: 25) in EN arm and 60% (CR: 3, PR: 20) in CEF arm after the completion of 4 cycles of neoadjuvant chemotherapy. There was no case of progressive disease during chemotherapy in both arms. Febrile neutropenia was observed in 20% of EN arm and 13% of CEF arm. Grade 3/4 granulocytopenia was observed in 46% in EN arm and 40% in CEF arm during the total of 184 cycles of EN arm and 152 cycles of CEF arm. Breast conserving surgery was performed in 40% of EN arm and 45% of CEF arm.

There was no significant difference in other toxicity profiles during neoadjuvant chemotherapy such as anemia, thrombocytopenia, and oral stomatitis. In summary, vinorelbine was an effective therapeutic agent with reasonable profiles in the neoadjuvant treatment of operable breast cancer. Results of the current study seem to mandate the prospect clinical trial which integrates vinorelbine in the adjuvant setting.

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Results of cryosurgery in the treatment of patients with breast carcinoma

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Experimental studies have demonstrated the usefulness of cryosurgery for the breast cancer treatment. The aim of our study was to assess the efficacy of preoperative cryosurgery in patients with stage II–III breast carcinoma.

Materials and methods: From July 2000 eighty patients with stage II–III breast cancer (mean age 56.7 years) underwent operation, which consisted of preoperative cryotherapy with subsequent modified radical mastectomy (or organ-conserving surgery when appropriate). Control group consisted of 76 patients similar by the main prognostic features, who received conventional treatment. The temperature of the cryoprobe was decreased to minus 190°Celsius, duration of freezing was 10 minutes. The process of cryosurgery was monitored by intraoperative ultrasonography.

Results: We observed no postoperative complications which could be attributed to cryosurgery. To the present date (range of follow-up is from 12 to 58 months) one local relapse (1.3%) was registered in the cryotherapy group, in control group 7 patients (9.2%) developed locoregional recurrence. Three-year overall survival in cryosurgery group was 85.7%, in control – 65.0% ($p > 0.05$), 3-year relapse-free survival was 84.1% in the cryotherapy group, 60.5% in control ($p < 0.05$).

Conclusions: Cryosurgery is safe and effective treatment option in patients with stage II–III breast cancer, allows to improve remote results and requires further clinical investigation.

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A pilot study of weekly versus 3-week docetaxel in combination with capecitabine in patients with anthracycline-pretreated metastatic breast cancer (CHN-TAX 614)

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Purpose: Capecitabine in combination with docetaxel given every 3 weeks has shown a high degree of activity in anthracycline-pretreated metastatic breast cancer (MBC), but with high toxicities. To improve the therapeutic