P74 Evaluation of clinical response to neoadjuvant chemotherapy of large primary breast tumours (≥3.5 CM) and correlation with magnetic resonance imaging

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Goal of the Study: To compare clinical response and response on magnetic resonance imaging in primary breast cancer patients, treated with neoadjuvant chemotherapy.

Methods: 30 patients with primary breast cancer clinically more than 3.5 cm diameter were included in a prospective study. Neoadjuvant chemotherapy consisted of 3 cycles of CMF. Clinical measurement of the tumour and magnetic resonance imaging was done before chemotherapy and 2 weeks after de last cycle. A T1-weighted 3D FLASH sequence at 1 T was used for imaging both breasts before and 8 times after i.v. application of 0.1 mmol/kg body weight gadopentetate dimeglumine. The tumour volume with strongest signal enhancement was calculated from subtraction images.

After the first MRI and before chemotherapy was started, an open biopsy and axillary dissection was done, to confirm the diagnosis and the staging of the primary breast cancer. Clinical response was evaluated according the criteria of the WHO and compared with response on MRI. Complete responders were compared with histologic results of definitive surgery.

Results: 1.

	Physical examination	MRI	Histologic examination
No/minor response	10	11	–
Partial response	9	15	–
Complete response	11	4	4

2. After neoadjuvant chemotherapy 18 patients had a mastectomy, 12 patients could have a breast conserving surgery.

Conclusions: (1) No or minor clinical response correlated well with no or minor response of the tumour on MRI.

(2) Complete responses on MRI were confirmed by complete absence of invasive tumour on histoplathologic examination.

(3) Complete response on physical examination is not a reliable parameter, as less than 40% of these patients had complete responses on MRI and on histology. So adequate surgery can not be mitted after a clinical complete response.

(4) MRI is a valuable tool in the assessment of response to neoadjuvant chemotherapy. It can be helpfull in the decision whether a patient can be offered a breast conserving surgery or not.

P75 Neoadjuvant chemotherapy with paclitaxel (P) in breast cancer, T 3/4, N+ M0

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Introduction: P, is an active agent in Metastatic Breast Cancer (MBC) and have demostrated antitumoral activity in anthracycline resistant MBC. Between 10/95 and 11/96, 8 unpretreated patients (pts) with Breast Cancer, stage: T 3/4, N+, MO, were entered in this study to assess eficacy, toxicity and feasibility of P.

Methods: Pts characteristics were, median age 53 y (range 42-68) performance status (ECOG) 0, 7; 1, 1; premenopause 3, postmenopause 5, T3, 3; T4, 5; hormonal receptors: positive, 5; negative, 3. Treatments consists of: P.250 mg/m^2 IV, over 3 hours, every 21 days for 4 cycles, pts who responded followed modified radical mastectomy, chemotherapy and radiotherapy.

Results: All pts were evaluable for toxicity and response. Toxicity (WHO): granulocitopenia G3, 4; G4, 4; alopecía G4, 8; Response was assesed clinically and radiologically. PR, 7; SD, 1; the pathological evaluation of the disease were: minimal in 3, moderate in 4, extensive en 1. In conclusion P, is an active regimen used us Neoadjuvant Chemotherapy in Breast Cancer, stage T3/4, N+ M0, with pathological response and acceptable toxicity.

P76 Multimodality therapy of 128 patients with locally advanced breast cancer in the era of mammography screening using standard FEC-prognostic and therapeutic implications

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One hundred and twenty-eight patients with locally advanced breast cancer including inflammatory breast cancer were given a multimodal therapy between 1991 and 1994. Four to six courses of preoperative 5-fluorouracil (600 mg/m^2), epirubicin (60 mg/m^2), cyclophosphamide (600 mg/m^2) (FEC) q three weeks were given, followed by modified radical mastectomy or sector resection and axillary exploration. Nine percent of the patients received preoperative radiotherapy, due to an insufficient effect by the FEC therapy. Three to five adjuvant FEC courses were given in addition to postoperative radiotherapy. The FEC cycles were replaced by concomitant cyclophosphamide (850 mg/m^2) q three weeks during radiotherapy. Tamoxifen, 20 or 40 mg daily, were given to one third of the patients at the end of the multimodal therapy. Clinical responses were observed in 60% of the patients with 55% in partial response (PR) and 5% in complete response (CR). Stable disease (SD) was seen in 40% of the patients. No patient had progressive disease (PD) preoperatively. At the end of the multimodal therapy 96% were clinically disease-free. No treatment-related clinical cardiac disease or toxic death were observed.

The median follow-up was 37 months. Median disease-free survival (DFS) was 29 months and overall survival (OS) was 54 months. The actuarial 5-year DFS and OS were 36% and 49%, respectively. Loco-regional relapse was seen in 20% and 53% had systemic relapse.

Univariate analyses revealed a significant prognostic difference according to clinical stage in favour of less advanced stages. Clinical/biological factors with a significant worse prognosis were inflammatory breast cancer and peau d'orange. Patients receiving below 60% and 75% of intended dose-intensity had a statistically significantly worse prognosis with reference to DFS and OS, respectively.

P77 7-Year follow-up results of preoperative CMFAV in complex treatment of patients with locally advanced breast cancer

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With purpose to determine efficacy of complex treatment modality with preoperative CMFAV chemotherapy regimen 63 patients with locally advanced breast cancer T2-4N0-2M0 were entered in our study between 1981 and 1989. Age: 26–61 years. All patients were treated with 1 cycle of preoperative CMFAV (adriamycin 40 mg/m^2 i/v, days 1, 8, 15, 21, vincristin 1 mg/m^2 i/v, day 1, methotrexate 30 mg/m^2 i/v, day 8, 5-flourouracil 600 mg/m^2 i/v, day 15, cyclophosphamide 400 mg/m^2 i/v, day 21). Modified radical mastectomy was performed in all cases in three weeks after chemotherapy. Postoperative treatment consisted of 4 cycles of VAM (vincristin 1 mg/m^2 i/v day 1, adriamycin 40 mg/m^2 i/v, day 2, methothrexate 30 mg/m^2 i/v, day 3.) in 57 cases. 5 patients were treated with CMF (cyclophosphan 150 mg/m^2 i/m, days 1–8, methothrexate 40 mg/m^2 i/v, days 1, 8, 5-flourouracil 600 mg/m^2, i/v, days 1, 8) postoperatively. In 1 patient there was no chemotherapy after operation. In 3 cases postoperative radiotherapy was also administered. 37 patients with ER positive tumours received hormonotherapy. In premenopausal women prednisolone or tamoxifen were administered after ovariectomy. Postmenopausal patients received tamoxifen 20 mg/day for 2 years. At follow-up time of 7-years 31 (49.2%) patients have relapsed and 13 (20.6%) patients have died. 7-year disease and overall survival was 47.7 and 75.04% respectively. Our date suggest that complex treatment modality with preoperative CMFAV regimen produced an excellent follow-up results of treatment in patients with locally advanced breast cancer.

P78 Primary chemotherapy in conservative treatment of stage II breast cancer patients

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The aim of this article was to evaluate the role of primary chemotherapy in conservative treatment of stage II breast cancer patients.

Since 1994 03 01 till 1997 09 01–100 stage II (T_2N_{0-1}) breast cancer patients, aged 28–50 years, were treated by conservative treatment. Patients were randomized into 2 groups. Group one: 2 cycles of primary chemotherapy (CMF), conservative surgery (plastic quadrantectomy), irradiation, adjuvant chemo/hormonotherapy. Group two: conservative surgery (quadrantecomy), irradiation, adjuvant chemo/hormonotherapy.

In 26% of patients group I (with primary chemotherapy) was detected partial or complete response. The results of 3.5 years follow-up are: in group I (with primary chemotherapy) local recurrence was diagnosed in 1 patients (T_2N_0) – 2%. Distant metastases were detected in 1 patients (T_2N_0) – 2%. In group II (without primary chemotherapy) local reccurences were diagnosed in 3 patients (T_2N_0 – 1 patient; T_2N_1 – 2 patients) – 6%. Distant metastases – in 4 patients (T_2N_0 – 1; T_2N_1 – 3) – 8%.

According to our preliminary data, primary chemotherapy prolongs (disease free survival) for stage II breast cancer patients.