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ORAL

Family history of breast cancer and local recurrence after breast conserving therapy

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Purpose: We investigated the impact of family history of breast cancer (BC) on local recurrence (LR) risk after breast conserving therapy (BCT).

Methods: The study was performed within the framework of a multicenter case-control study (BORST) of risk factors for LR after BCT. Family history (BC in first and/or second degree relatives) was assessed for 218 BC patients with LR (cases) and 480 BC patients without LR (controls). Detailed histological features were assembled by revision of the primary tumour.

Results: The risk of LR was not significantly different between familial and sporadic breast cancer patients (OR 0.65 (95% C.I. 0.39–1.06)). Familial patients tended to have a smaller tumour diameter ($p = 0.12$) and lower histological grade ($p = 0.08$). Adjustment for these factors and age at onset did not essentially alter the results (OR_{adj} 0.68 (0.37–1.26)). Separate analyses according to age at onset $<$ and $>$ 50 years and time and location of LR did not show different results.

Conclusions: The presence of a positive family history of BC is no risk factor for LR after BCT. This might be different in (subgroups of) truly hereditary cases.

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POSTER

Epirubicin (EPI) and vinorelbine (VNR): High activity, dose dense regimen for primary breast cancer

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Neoadjuvant/adjuvant chemotherapy studies generally employ regimens that have appeared to be the most active against the same tumor in advanced stages. In a previous study, we showed the efficacy and tolerance of EPI and VNR plus G-CSF in untreated metastatic breast cancer patients, obtaining a 77% response rate (ASCO '97). We therefore wanted to examine this combination in a neoadjuvant setting. Between January 1997 and January 1998, 48 patients (pts.) with locally advanced breast cancer were treated with EPI, 60 mg/m² on days 1 and 15 and VNR 25 mg/m²/week plus G-CSF; 150 mcg/m² on days 2, 4, 9 and 11. Therapy was administrated for three months.

Patient Data: Median age: 48 years (range: 29–72 yrs.), PS 0: 46 pts.; PS 1: 2 pts.; Premenopausal status: 30 pts.; Postmenopausal status: 18 pts.. The diagnosis of a carcinoma was always confirmed by cytology.

Toxicity: All the pts. are evaluable for toxicity. Neither febrile neutropenia nor infection were observed, although grade 3–4 neutropenia affected 17 pts. (35%). No other serious hematologic toxicity was present. Four pts. had grade 3 nausea and vomiting and two pts. had grade 3 stypsis.

Results: response was evaluated in 36 pts. A pathological complete response (CR) was obtained in 5 pts. (14%), a partial response (PR) in 30 pts. (83%) and stable disease (SD) in one pts. (3%). The overall response rate was 97%. There were no cases of progressive disease (PD). Conservative surgery could be performed in 8 of the pts. (22%).

After primary chemotherapy plus surgery the following stages and node involvement were determined: stage 0: 2 pts., I: 4 pts., IIA: 23 pts., IIB 6 pts. and IIB 1 pt., N₀ 10 pts., N₊ 1–3 14 pts. (N_{0/1-3}: 67%); N₊ 4–9: 8 pts., N₊ \geq 10: 4 pts.

Conclusions: The combination of EPI, VNR and G-CSF appears to be highly effective and well tolerated in a neoadjuvant setting.

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POSTER

Concurrent paclitaxel and radiation in locally advanced breast cancer

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Purpose: 1) To study primary paclitaxel during radiation as a first-line treatment for locally advanced breast cancer, 2) to obtain pre-treatment tumor biopsies to explore molecular determinant of pathological response, 3) to measure in selected patients the kinetics of paclitaxel effects on cell cycle.

Methods: Locally advanced Stage IIIA or IIIB breast cancer patients are eligible. We measured tumor mitotic and apoptotic indexes by obtaining sequential fine needle biopsies of breast cancers at 24 h, 48 h, 72 h and 96 h after paclitaxel. The data generated supported the design of a regimen of twice a week paclitaxel (30 mg/m² over one hour) and RT (50.40 Gy/ 28 fractions) to the breast and regional nodes.

Results: A total of 15 patients were accrued, so far. The preliminary clinical and pathological results from the first ten evaluable patients are available. No grade IV toxicities occurred. The only grade III toxicity consisted of in field wet desquamation in one patient. One patient developed grade II esophagitis. All patients achieved a clinical response: 4 CR, 6 PR. Two of the ten patients achieved pathological complete response (clearance of invasive cancer in the breast and axillary contents) and 4 achieved a pathological partial response (residual microscopic foci of invasive cancer).

Conclusion: The combination of twice a week paclitaxel and radiation is well tolerated and constitutes a promising primary management for locally advanced breast cancer.

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POSTER

Combination of oral idarubicin and cyclophosphamide in the treatment of advanced breast cancer

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Background: Oral idarubicin has been shown to be an effective treatment option especially in older patients with advanced breast cancer. In this study an oral combination therapy of idarubicin and cyclophosphamide was performed.

Patients and Methods: 49 patients with stage IV breast cancer were treated with oral idarubicin 25 mg/d on two consecutive days followed by oral cyclophosphamide 200 mg/d for 3 days, every 21 days.

Results: Out of 40 Patients that received at least 2 cycles, 17 showed an objective response rate with 3 complete remissions. In 3 patients therapy had to be stopped because of grade 4 myelotoxicity. Nausea and vomiting as well as alopecia was generally low and tolerance was good.

Conclusion: Combination of oral idarubicin and cyclophosphamide is a safe and effective treatment, that may improve the quality of life of breast cancer patients with poor venous access.

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POSTER

Combination chemotherapy with paclitaxel (T) and epirubicin (E) for metastatic breast cancer (MBC): A phase I–II study

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Aim: to evaluate response rate and toxicity of a regimen including administration of (E) followed by (T).

Methods: 48 patients (pts) with MBC previously untreated for metastatic disease entered our study. 37 pts received adjuvant therapy, including 7 pts treated with anthracyclines (there had been twelve or more months of disease free survival after adjuvant therapy). Pts characteristics included: median age 54.6 y (30–73), ECOG \leq 2, visceral (56.8%) and bone (43.2%) metastases. Pts were treated every three weeks with (E) day one 60–90 mg/m² and (T) day two 175–200 mg/m²; (E) and (T) were administered by 30' and 3 hours standard i.v. infusion respectively and pts were premedicated with standard antiallergic and antiemetic regimens.

Results: actually 48 pts are evaluable for toxicity and 39 for response. A total of 309 courses of chemotherapy was administered (1–8, average 6.5).