We have observed 24 relapses (11.6%) equally balanced between pre and postmenopausal patients.

Toxicity was generally acceptable, no particular cardiac toxicity was observed.

PP-5-19 Intensification Chemotherapy (IQ) with Autologous Peripheral Blood Progenitor Cell (PBPC) Support in Patients with Breast Cancer: Results of the Transplantation Procedure

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From Dec. 93 to February 96, 25 p. with breast cancer were included in our program of I.Q. with autologous PBPC support. *Methods:* On day 14, after a course of CAF chemotherapy, priming was given with G-CSF 10 μg/kg/day × 7 for mobilization, with planned apheresis on days 5. (& 6–7 if needed), following the surgical implantation of a double lumen CVC, performed with the use of one of two cont. flow blood cell separators (Baxter CS 3000 & Cobe Spectra), until a number of 7 × 10^8/kg MNC were reached. The product was reconstituted with DMSO & autologous plasma, and cryopreserved (controlled rate freezing to −197°C). I.Q. was given as an outpatient procedure with Carboplatin 800 mg/m^2, Mitoxantrone 25 mg/m^2 and Thiotepa 600 mg/m^2 on days −5 to −3.; P. were admitted to individual rooms with double barrier nursing on day −1 and each bag of PBPC infused in less than 15 min. under cardiovascular control. Antiemetic was given with Granisetron & Dexamethasone. Infection prophylaxis was made by Cotrimoxazole, Acyclovir, Fluconazole, and after day +2, GCSF 5 μg/kg until ANC > 1.0 × 10^9 × 2 days. Pentoxiphylline was added for 2 months. *Transplantation Results:* Age (median): 44 (26–53); Stages: IIB: 12; IIIA: 1; IIIB: 7; IV: 5; Apheresis: (median): 2; Hospitalization days: 12 (10–16). *Product of cells infused/kg* (1 p. was excluded for this analysis because CD34 pos. selection was used) (median): M. nucleated Cells (MNC) 7.46 × 10^8, CFU-GM: 34.1 × 10^4 (in 12 p.), CD34+: 7.05 × 10^6. Viability (Trypan blue): 90%. *Hematologic recovery:* days with ANC < 0.5 × 10^9/l: 7 (5–9); platelets < 20 × 10^9/l: 4 (1–7). *Toxicities:* Hypertension (post-infusion) > 30 mmHg: 11 p; Mucositis GII: 4 p. GIII: 1 p; Vomiting: GIII: 5 GII: 10 p; Diarrhea: GIII: 3 p, GII: 3 p.; Hepatotoxicity: GII 1 p; Flebitis > 5 days: 2 p; Low Back pain during G-CSF priming: 21 p, *Complications:* Fever > 38.5°C: 11 p; Days with empiric antibiotics: 3.8 (0–9); *Blood support:* Single-donor platelets products: 3 (1–5); Packed red cells: 1.6 (0–2). Peritransplantation mortality: 0; *Outcome (N:25):* With a median follow up of 14 m. (2–26) 4 of the 5 p. in stage IV have recurred at m. 12, 1, 1, & 6 months of transplantation and one is in RC after 22 m. For the 20 p. in the adjuvant setting, 1 recurred at 11 m. *Conclusions:* Autologous PBPC support of this I.Q. therapy was associated with low morbidity and the phases of mobilization, apheresis and intensification could be given in an outpatient setting, reducing thus the cost of the procedure. The outcome for the first 5 patients in stage IV appears to be negative. Further studies with longer follow-up & more patients are needed.

PP-6. Prognosis 1: Clinico-Pathological Factors (September 12)

ORAL PRESENTATIONS

PP-6-1 Time Since Birth is a Prognostic Factor in Primary Breast Cancer

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The Danish Breast Cancer Cooperative Group has since 1977 collected population-based information on primary clinical data, treatment regimes, and follow-up status on Danish women with breast cancer. Detailed information on pregnancy history was added from the Danish Civil Registration System and the National Birth Registry. Included in the study were 5,954 patients who at the time of breast cancer diagnosis were 45 years of age or less. Women classified with low-risk breast cancer, i. e. lymph node negative cancers, less than 2 years after having given birth had a crude survival of 75.0 percent (5-year) and 55.6 percent (10-year), respectively, compared with 88.5 percent (5-year) and 77.8 percent (10-year) for women whose last child birth were more than 2 years prior to their diagnosis. After adjusting for age, reproductive factors, and stage of disease (tumor size, axillary nodal status, and histologic grading), a diagnosis less than 2 years since birth remained significantly associated with a poor survival (RR = 1.64, 95% CI: 1.28–2.09). Stratified analyses showed that the effect was independent of age at diagnosis, tumor size, and nodal status.

These data illustrate a growth-enhancing effect of pregnancy on breast cancer. A diagnosis of breast cancer less than 2 years after having given birth is associated with a particularly poor survival irrespective of the stage of disease at presentation. It should be considered to offer the subset of patients, who are otherwise classified as having low risk disease, systemic adjuvant treatment.

PP-6-2 Incidence and Prognostic Value of Routine Clinical Parameters in 2273 Patients with Primary Breast Cancer Treated between 1978–1990

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The clinical data of 2273 pts with primary breast cancer and known ER status were collected: mean age 56 yr (22–89 yr); premenopausal 41%; T_1 = 43%, T_2 = 45%, T_3/T_4 = 11%; N^0 = 46%, N^{1-3} = 27%, N^{4-9} = 17%, $N \geq^{10}$ = 10%; ER^+ = 78%, PgR^+ = 72%; median follow-up 6 yr; adj. syst. ther. 24%; recurrence rate 47%. The percentage of T_1 tumors increased from ± 30% before 1985 to 40–54% after 1985 while N^0 tumors increased from ± 40% to 50% in the same period. Within the group of 962 patients with T_1 tumors 36% were node-positive (N^{1-3} = 24%, N ≥ 4 = 12%). By multivariate analysis tumor size ($p < 0.0001$), nodal status ($p < 0.0001$), age ($p < 0.0001$), menopausal status ($p < 0.03$) and ER/PR status ($p < 0.001$) were independent prognostic factors, while high grade predicted poor survival. Although in the pT_1-category there was no difference in survival between N^0 pts and pts with only one positive node, relapse-free survival (RFS) decreased by increasing number of positive nodes. Pts treated with adjuvant chemotherapy showed better survival curves than not adjuvantly treated pts within all N^+ subcategories. The small discriminatory effect of ER and PgR status was most significant after 3 yrs of follow-up, but disappeared after 7 yrs. The duration of RFS, ER and PgR status and site of metastasis were predictive factors for duration of postrelapse (progression-free) survival.

In conclusion: although new cell biological factors independently add, classic clinical parameters are still of important value for prognosis of pts with breast cancer (supported by Dutch Cancer Society, DDHK 92–04).

PP-6-3 The Selection of Patients with DCIS for a Clinical Randomised Trial: Differences between Large Participating Centres

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In multicentre randomised trials the interpretation of selection criteria may differ between participating centres, which will result in different entry rates. This "institutional" selection bias may also explain differences in outcome of a trial when evaluated per centre.

We analysed the possible influence of institutional selection in four institutes participating in the EORTC 10853 trial. This trial compares radiation therapy versus no additional treatment after local excision for ductal carcinoma in situ of the breast. The trial was started in 1986. Eligibility criteria for the trial are: age < 70 years, no previous malignancy including contralateral breast cancer, complete excision of the lesion, DCIS < 5 cm and absence of microinvasion and of Paget's disease of the nipple. The four institutes have the disposal of a complete registration of all patients with breast cancer treated at the centre. Medical histories of all cases of DCIS diagnosed during the period the centres participated in the trial were reviewed. The following parameters were analysed: the total number of patients with DCIS treated, the number of patients entered and the number of patients eligible for the trial. Main reasons for non-entry were contralateral breast cancer, size of DCIS, and patient's refusal. This, however, does not explain sufficiently the different entry rates, which varied from 7 to 66%.