control over the body or feelings of vulnerability emerged as major theme, and thus a large number of items in the questionnaire measured this aspect of body image. The questionnaire was distributed to 360 women with breast cancer attending oncology clinics in a consecutive fashion. The questionnaire was returned by 308 subjects (85.6%). The mean age of the group was 57 years. 38% of respondents had a mastectomy, 55% a lumpectomy, 7% breast reconstruction and 13% had metastatic disease.

42% of respondents stated agreed that they felt their body had been invaded, 29% agreed that they felt there was a time bomb inside of them and 20% often felt that something was taking over their body. 20% of respondents stated that they often felt damaged, and 28% often felt their body had let them down. 27% often worry that the cancer is spreading, 26% often worry about minor aches and pains while 35% of respondents felt they often need reassurance about their health. 35% felt in control of their body only infrequently or never.

A significant number of women with breast cancer appear to lack a sense of control over their bodies. Further research is being conducted to compare these findings to a population of women without breast cancer.

PP-4-40 Histologic Findings in Prophylactic Mastectomy Specimens from Women with Hereditary Risk Factors

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A family history is one of the major risk factors of breast cancer. We studied the histologic findings in prophylactically removed breasts. Prophylactic bilateral mastectomy was performed either because of a proven BRCA1 mutation, or because of psychological distress as a consequence of a high risk based on the pedigree. In a number of 22 mastectomy specimens a high frequency of fibrocystic changes and proliferative breast disease was observed such as: florid (46%) and atypical (14%) hyperplasia, sclerosing adenosis (36%), adenosis in general (82%), fibroadenomas (23%), papillomatosis (14%) and microcalcifications (41%). Also one invasive breast cancer (4%) with a diameter of 0.7 cm was found, not detected by physical examination and mammography before surgery. These changes were more frequently found than would be expected from known literature data on benign breast disease in general.

In conclusion: genetic susceptibility may cause fibrocystic and/or proliferative breast disease preceding breast cancer (supported by the Dutch Cancer Society; DDHK 95-953).

PP-4-41 The Age Distribution and Biological Characteristics of Interval Cancers in the North West Region of the NHSBSP

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The NHS breast screening programme screens women aged 50–64 every three years. Eventual mortality reduction will be influenced by the incidence and biological characteristics of interval cancers occurring in the programme. We found that the incidence of interval cancers in the third year was 65% of background incidence indicating that the three year interval is too long.

Of 471 interval cancers 73% were infiltrating ductal carcinomas of which 54% were grade 3 tumours. Over 70% of the invasive carcinomas were greater than 15 mm.

The incidence of interval cancers is significantly higher in women aged 50–59 than in women aged 60–64 but their characteristics do not vary with age. These results suggest that for women aged 50–59 the high incidence of interval cancers will greatly reduce the benefit of screening but for women over the age of 60 screening with a three year interval may still produce a mortality reduction similar to that achieved by the Swedish Two County Trial.

PP-5. Adjuvant Systemic Treatment and Intensive Chemotherapy (September 12)

ORAL PRESENTATIONS

PP-5-1 Preliminary Analysis of a Randomized Phase II Study of High-Dose Chemotherapy in High-Risk Breast Cancer

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To prepare for a large multi-center trial of high-dose chemotherapy in high-risk breast cancer, a randomized single-institution study was performed in the Netherlands Cancer Institute between May 1991 and December 1995. Eligible patients had stage II or III breast cancer with a tumor-positive apical axillary lymph node at infraclavicular biopsy, were < 60 years of age and had a WHO performance status of) or 1. The conservative treatment arm consisted of 3 courses of FEC: fluorouracil (500 mg/m^2), epirubicin (120 mg/m^2) and cyclophosphamide (500 mg/m^2). Patients with at least a minimal (clinical) response subsequently underwent definitive surgery (including an axillary lymph node dissection), a fourth course of FEC, radiation therapy and two years of tamoxifen. Patients in the experimental arm received identical treatment, except that the post-operative FEC course was combined with filgrastim to mobilize peripheral blood progenitor cells (PBPC) and was followed by high-dose chemotherapy with CTC: Cyclophosphamide (6 g/m^2), thiotepa (480 mg/m^2) and carboplatin 1600 mg/m^2).

Ninety-five patients were enrolled in the trial and 79 were randomized after surgery: 38 to undergo conventional treatment only and 41 to receive CTC + PBPC transplantation. 35 of the these 41 patients were actually transplanted, all others were managed conservatively. There were no toxic deaths. With a median follow-up of 31 months (range 4–59) and analyzed on an intention-to-treat basis, overall and progression-free survival (PFS) in both groups are identical (projected 4-years survivals 75% and 80%, respectively). Patients who were not randomized (11 × refusal, 4 × lack of response to FEC, 1 × myelodysplasia) did worse, with a projected 4-year PFS of only 20%. The early analysis of this trial does not (yet?) predict a major survival advantage for high-dose therapy.

PP-5-2 Neo-Adjuvant High-Dose FEC Regimen (H-FEC) with G-CSF (G) for Large Early Breast Cancer

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Background: In order to increase conservative surgery in women with resectable breast cancer (T < 3 cm) after neoadjuvant chemotherapy (53% Spielmann M, ASCO, 1990), we included in a phase II study 46 consecutive patients (pts) with large early non inflammatory breast cancer (tumor size > 30 mm). Treatment consisted of 5-FU 1,000 mg/m^2, Epirubicin 100 mg/m^2 and Cyclophosphamide 1,000 mg/m^2 day 1, with G-CSF 5 μg/kg/d days 5 to 12. Courses were q 21 days for a total of four before surgery and radiotherapy. All pts had an histologic procedure (tru-cut or biopsy) before inclusion and gave an informed consent.

Patients characteristics: Mean age 46 years (range 29–64); Mean tumor size (T) 47 mm (range 35–75). Stage IIA: 13 pts, IIB: 15 pts and IIIA: 18. Hormonal receptors (+) in 25, (−) in 14, unknown for 7 pts. Thirty-six pts presented a ductal carcinoma, 3 a lobular one, and 7 an undifferentiated. *Results:* Median delivered Dose Intensity from planned was 97%.. Forty four pts (95%) completed the programmed schema (4 cy). No pts progressed on treatment. Breast conservative surgery could be performed in 28 pts (61%). We found 6 complete pathologic remission (13%). Hematological toxicity (assessed all 3 days) was mild; 13 pts (28%) presented Gr IV neutropenia with 5 febrile aplasia (4 pts). No Grade IV non-hematological toxicity was seen, with no related toxic death.

Conclusion: H-FEC + G showed a high rate of conservative surgery and of histological CR with no severe side effects. A randomised phase III study (*FEC-60* Vs *H-FEC + G*) for large early breast cancer (T > 3 cm) is actually ongoing.