administrated and a group not administrated tamoxifen. The two groups showed no differences in back ground factors. In the observation period of 34 weeks, localized recurrences were not found in the tamoxifen group but appeared in two patients in the untreated group. The premenopausal ER (+) patients were all comedo type and EIC (+). Concomitant use of tamoxifen appears to be useful as postoperative treatment in premenopausal patients undergoing breast preservation therapy.

PP-5-14 FEC-75 Plus G-CSF in Locally Advanced Breast Carcinoma

A. Artal*, V. Alonso, O. Gallego, A. Herrero, A. Tres [1], D. Isla [1], M. Delgado, A. Antón-Torres. [1] *Medical Oncology, H Miguel Servet & Clínico, Zaragoza, Spain*

Aim. – To assess efficacy and tolerability of chemotherapy (CT) given every 14 days to increase dose-intensity (DI) and reduce time to surgery in patients with T3/T4 and/or N2 breast carcinoma.

CT scheme. – FEC-75 (5-FU 600 mg/m^2, epirubicin 75 mg/m^2, ciclophosphamide 600 mg/m^2) day 1st plus filgrastim 30 mU SC, days 3 to 12. Courses were repeated every 14 d up to 4 courses (c).

Patients. – From April/94 40 patients (p) have been included in 4 hospitals: median age 54 y (32–65); ECOG 0 40 p; post-menopausal 21 p; T1–2 6 p, T3 19 p, T4b 6 p, T4d 6 p; N0 13 p, N1 9 p, N2 15 p; G2 22 p, G3 8 p. Stages IIb 9 p, IIIa 15 p, IIIb 13 p.

Results. – Courses given: 119. Actual dose: 100% in every c. without delay (DI 150%). Non-hematological toxicity: N&V G2 35 c (29%), mucositis G1 6 c, flu-like synd G1 6 c, G2 1 c, alopecia 40 p. No cardiotoxicity (LVEF measured in 18 p). Hematological toxicity: On day 1 of the course, only 1 p had thrombopenia G1. anemia G1 12 p.

Responses (OR) en 22/35 p (63%): RC 5 p, RP 17 p, EE 13. No progressive disease. Surgery already performed in 33 p (mastectomy 25 p, conservative 8 p).

Conclusions. – FEC-75/14d × 3–4c + G-CSF showed high response rate without severe toxicity. Pathologic CR rate remains low. DI was significatively increased and time to surgery reduced. Radical surgical procedures were performed in all patients in our experience.

PP-5-15 Postoperative Adjuvant Randomized Trial Comparing Chemoendocrine Therapy, Chemotherapy and Immunotherapy for Patients with Stage II Breast Cancer

T. Morimoto*, M. Ogawa, K. Orita, K. Sugimachi, T. Toge, K. Dohi, Y. Nomura, Y. Monden, N. Ogawa. *Nishinihon Cooperative Study Group of Adjuvant Chemoendocrine Therapy for Breast Cancer of Japan*

The effects of using ftorafur (FT) or PSK (an immunotherapy agent) in combination with adjuvant therapy using mitomycin (MMC) + tamoxifen (TAM) were assessed in stage II, ER+ breast cancer patients. In stage II, ER– breast cancer patients the effects of adjuvant therapy using MMC + FT were compared with those using MMC + PSK. On the day of surgery, MMC (13 mg/m^2) was administered. ER+ patients received one of three regimens, starting 2 weeks after surgery: regimen A (30 mg/day of TAM), regimen B (30 mg/day of TAM and 600 mg/day of FT) or regimen C (30 mg/day of TAM and 3 g/day of PSK). ER– patients received either regimen D (600 mg/day of FT) or regimen E (3 g/day of PSK). Of the 540 ER+ patients, 525 were evaluated. The 5-year survival (OS) was higher for patients who received regimen B than for those who received other regimens (P = 0.063). The 5-year relapse-free rate (RFS) was higher for regimen B than for other regimens (P = 0.010). Stratified analysis revealed better results with regimen B in premenopausal patients and patients positive for lymph node metastasis. Of the 376 ER– patients, 364 were evaluated. There was no significant difference in OS or RFS between the D and E regimens.

PP-5-16 A Study of Postoperative Adjuvant Chemotherapy of 5′-DFUR in Breast Cancer Patients (1st Report) — On Compliance and Safety — "The 5′-BC Study Group" (5′-DFUR Adjuvant Chemotherapy for Breast Cancer Study Group)

H. Koyama*, O. Abe, J. Uchino, W. Hayasaka, R. Abe, M. Izuo, K. Enomoto, T. Tominaga, H. Watanabe, M. Yoshida, T. Taguchi, T. Senoo, T. Toge, Y. Monden, T. Hattori, Y. Nomura, K. Sugimachi, H. Nakazato, Y. Ohashi, S. Miura, T. Morimoto, K. Asaishi, I. Kimijima, J. Ohta, H. Sonoo, M. Toi, S. Yamaguchi. *The 3rd Department of Surgery, Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka, Japan*

Introduction 5′-deoxy-fluorouridine (5′-DFUR), an analogue of 5-fluorouracil synthesized by Cook et al. in 1976, is used orally to treat stomach, colorectal, cervical, bladder, and breast cancers in Japan. To assess the usefulness of postoperative adjuvant 5′-DFUR chemotherapy in breast cancer, we conducted a controlled comparative study at 153 institutions; control groups received only surgical resection. Subjects were of T < 3 cm, N0 or N1a, M0 and Brt + Ax or over after gross curative resection. From June 1990 to December 1992 (2 years and 7 months), 1217 patients were registered in the study. The report rate of cumulative follow up data was 97%.

Methods Patients were randomly assigned to a repetitive or intermittent dosage group. Repetitive dosage: Method Y (5′-DFUR from 2 wks. after operation at 1200 mg/day × 4 wks., discontinuance for 2 wks. followed by 600 mg/day × 20 wks.) and method X (surgery only). Intermittent dosage: Method B (5′-DFUR from 2 wks. after operation at 1200 mg/day × 4 wks., discontinuance for 2 wks., 1200 mg/day × 2 wks. alternated with 2 wks. discontinuance until 28 wks. after operation) and Method A (surgery only).

Results Compliance was favorable: 91.1% of Method Y and 88.0% of Method B patients achieved 80% or more of the drug administration rate (Actual total dose/scheduled total dose) in our protocol. While incidence of adverse reactions was 24.8% (Method Y) and 27.2% (Method B), most adverse reactions were mild (grade 1 or 2) gastrointestinal symptoms, e.g., diarrhea, etc. Although follow-up results continue to be compiled (median observation time, 4.3 years), interim findings are available on request.

PP-5-17 High-Dose Cyclophosphamide (CTX), Mitoxantrone (MXT), and Paclitaxel (Taxol®, TXL) for the Treatment of Metastatic Breast Cancer (MBC) with Blood Cell Support

S. Glück* [1], A. Arnold [2], P. Cano [1], M. Dorreen [1], C. Germond [1], P. Lopez [1], H. Dulude [3], G. Gallant [3]. [1] *NEORCC, Sudbury, Ontario, Canada;* [2] *HRCC, Hamilton, Ontario, Canada;* [3] *BMS Canada, St. Laurent, Quebec*

A Phase I study using CTX 6 g/m^2, MXT 70 mg/m^2, in combination with TXL at a starting dose of 250 mg/m^2 in dose escalation for the purpose of determining dose limiting toxicity (DLT), maximum tolerated dose, and efficacy of this drug combination in a transplantation setting with pharmacokinetic analysis of TXL is being performed. Patients between the age of 18–55 with MBC not previously treated with cytotoxic drugs for metastatic disease are eligible. So far, 45 patients were enrolled and 31 patients have completed the treatment. The blood cell transplantation and recovery time was delivered completely in an out-patient setting. Recovery for ANC ≥ 0.5/nl was 10–16, median 12 days. Recovery for platelets ≥ 20/nl was 18–20, median 12 days. 15 patients developed neutropenic fever that required IV antibiotics. Up to the 3rd dose level of TXL, few patients have experienced grade II and III toxicity other than, hematotoxicity. In the 4th dose level, 6 patients were treated; 3 of them experienced DLT; therefore, an extended infusion schedule delivering the 400 mg/m^2 TXL over 6 rather than 3 hours is used. This study is ongoing.

PP-5-18 Adjuvant Epirubicin and CMF +/– Hormonotherapy in More than 3 Nodes Positive Breast Cancer Patients: Preliminary Data

A. de Matteis*, G.D. 'Aiuto, M. Rinaldo, G. Landi, D. Montedoro, F. Nuzzo, V. Labonia, I. Falco, P. Frezza. *Istituto Nazionale Tumori, Naples, Italy*

206 patients with early breast cancer were treated with Epirubicin 110 mg/sqm iv d 1 q 3 weeks × 4 cycles followed by CMF (CTX 500 mg/sqm iv d 1–8, MTX 40 mg/sqm iv d 1–8.5-FU 600 mg/sqm i.v. d 1–8 q 4 weeks) × 4 cycles +/– Hormonotherapy: Goserelin depot sc every 28 days × 2 years in premenopausal patients and Tamoxifen 20 mg/os/day × 5 years in postmenopausal patients. Radiotherapy was given after conservative surgery.

Median age was 42 years in premenopausal patients and 59 in postmenopausal patients.