all 6 cycles at the prescribed dose, but 69% strictly respected intercycle intervals.

Mild digestive and cutaneous toxicity (grade 1 and 2) was observed in 50%. Major toxicity was neutropenia (grade 2 or 3) in 18 patients and 1 severe infection. The 3 year actuarial survival rate was 87%. No local relapse was observed. Metastases occurred in 6 patients.

These preliminary results show that this concomitant association is safe although compliance to chemotherapy should be improved.

74 PUBLICATION

CONCOMITANT ADJUVANT CHEMOTHERAPY (FNC REGIMEN) AND RADIOTHERAPY IN OPERABLE STAGE II BREAST CANCER (O.B.C.)

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The purpose of multimodality treatment including simultaneous radiochemotherapy is to reduce the total length of the adjuvant treatment after surgery. Aims of study were to evaluate the compliance, global toxicity and local cutaneous side effect. The treatment scheme is F.N.C (F: Flourouracil 500 mg/m^2, N: Mitoxantrone 12 mg/m^2, C: Cyclophosphamide: 500 mg/m^2) every 21 days. Six cycles for N+, 4 cycles for N− with poor prognosis (RH- or SBR III). Radiotherpy is indicated by the consensus of the "Societe Française de Radiotherapie Oncologique" S.F.R.O. (50 Gy/25 fractions/5 weeks, 15 Gy overdose when T > 10 mm).

We report a feasibility study in 154 pts with O.B.C. included from May 90 to October 95 Median age: 49, 5 y (29–72), postmenopausal: 46.8%; premenopausal: 52.6%; Performance Status O: 96.7%, 1: 2%, unknown: 1.3%, Radical surgery: 29.9% conservative: 69.5%, N−: 29.9%; N+: 70.1%. Ductal carcinoma: 85.7%, lobular: 5.8%, SBR I: 2.6%, SBR II: 26.6%, SBR III: 65.6%.

Total number of courses was 773 (60.4% of pts received 6 courses). Full dose of N was administered to 84.4% of pts, F to 90.3%, C to 88.3%. Interval between 2 cycles was 21 days in 30.9% pts, 28 days in 45.4% pts, upper than 28 days in 23.7% pts. Median total radiotherapy dose was 50 Gy. Main toxicities observed (per pts) were: gastrointestinal grade 3–4: 4.6%, dysphagia: 27.9%, leucopenia grade 3–4: 12.3%, anemia grade 2: 2%, thrombocytopenia grade 2: 1 pt. A reversible cardiotoxicity occurred in 15 pts including extrasystole: 1 pts, low blood pressure: 2 pts, pericarditis 3 pts. Local toxicity was mild (grade ⩽ 1: 62.3%, grade 2: 16.9% and grade 3: 4.5%). No major pulmonary toxicity was observed. Quality of life (E.C.O.G scale) was performed to evaluate the repercussion of this treatment grade 0: 44.2%, grade 1: 34.4%, grade 2: 7.8% and grade 3 in 1 pt. Well acceptability of treatment in 51.9% of pts.

Mitoxantrone containing chemotherapy and postoperative radiotherapy can thus be combined in an adjuvant treatment program with good compliance and acceptable toxicity. Ongoing or further study of a large patients groups comparing various strategies of chemotherapy and radiation sequencing will be needed to confirm our data.

75 PUBLICATION

A PILOT STUDY OF ADJUVANT POSTOPERATIVE CHEMOHORMONAL THERAPY WITH 5-FLUOROURACIL, DOXORUBICIN, CYCLOPHOSPHAMIDE, VINDESINE AND TAMOXIFEN FOR RESECTABLE BREAST CANCER

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Adjuvant systemic therapies have proved effective to increase disease-free survival (DFS) and total survival at 5 and 10 years in patients with "resectable" breast cancer. However, the amount of the benefit is at best moderate. There is a need of more effective regimens.

We show the results of a pilot trial of postoperative adjuvant therapy with 6 cycles of 5-Fluorouracil 600 mg/m^2, doxorubicin 50 mg/m^2, cyclophosphamide 600 mg/m^2 and vindesine 3 mg/m^2 (maximum 5 mg), all endovenous on day 1, repeated every 28 days, plus Tamoxifen (20 mg/day) continued for 2 years (not in ER negative tumors). This schedule of chemohormonotherapy had been demonstrated highly active in metastatic breast cancer. Three-hundred and five patients (pts) have been treated. Menopausal status was: premenopausal in 93 pts and postmenopausal in 212. ER status was (+) in 90 pts, (−) in 61 pts and unknown in 154 pts. Twenty-three pts had node negative stage II tumors with peripheral blood or lymph vessel invasion (PBLI), 75 pts had 1 to 3 positive nodes, 33 pts had 4 to 10 positive nodes, 15 pts had 10 or more positive nodes and 159 pts had technically respectable stage III tumors +/− axillary nodes (N0, N1 o N2). (stage IIIA 87 pts and stage IIIB 72 pts). More than 90% of the patients received 6 cycles of chemotherapy at full dose. Median follow-up is now 44 months (80 pts followed for 5 years or longer). Actuarial 5 year DFS is 84% for N(−) stage II with PBLI; 79% for pts with stage II (1–3 nodes); 70% for pts stage II (3–10 nodes); 62% for stage II (>10 nodes) and 56% for stage III. DFS and total survival according to menopausal status and ER status will be presented.

We feel that such stimulating results in this uncontrolled pilot trial deserve testing in a randomized multi-institutional study.

76 PUBLICATION

ADJUVANT FOUR CYCLES OF EPIRUBICIN AND CYCLOPHOSPHAMIDE WITH RADIATION THERAPY IN OPERATED STAGE II–III BREAST CANCER

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Between April 1992 and March 1993, 96 operated patients with stage II–III breast cancer received adjuvant treatment consisting of Epirubicin (70 mg/sqm) and Cyclophosphamide (600 mg/sqm) I.V. every three weeks for 4 cycles and followed by locoregional radiation therapy. Median age was 41 (range 25–60). Sixty-eight patients were in stage II, 28 in stage III. Seventy-nine we premenopausal and 17 postmenopausal. WHO Grade 2–3 side effects were: Leucopenia 18%, and alopecia 60%. Cardioxicity was not observed.

After a median follow-up of 28 months, 18 patients presented recurrences (3 local and 15 distant) five patients died during the follow-up. Adjuvant combined 4 cycles of EC followed by radiation therapy is an affective treatment with high local and distant control, and shortens the treatment time in stage II–III operated breast cancer.

Small cell lung cancer

77 ORAL

RANDOMISED COMPARISON OF ALTERNATING OR SEQUENTIAL SCHEDULES OF CHEMORADIOTHERAPY IN LIMITED SMALL CELL LUNG CANCER (SCLC) TRIAL OF THE EORTC LCCG(08877)

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EORTC Lung Cancer Co-operative Group

Combined modality therapy is becoming standard treatment for "good prognosis" patients with SCLC but the optimal schedule and timing of thoracic irradiation is as yet unclear.

The EORTC LCCG has completed a randomised comparison of alternating (A) vs sequential (S) schedules of CDE chemotherapy and thoracic irradiation (50 Gy in 20 fractions) with identical total chemotherapy and radiation doses and overall treatment time; the schedule as the only variable. This trial will close on 31.3.1995. Three hundred and forty-nine patients have been randomised (174 in A, 175 in S), 11 were inelligible. Mean age was 60, M/F = 2/1, PS 0 (46%), 1 (47%), 2 (5%) and 3 (2%). Weight loss was < 10% in 76%. All these parameters are similar in both arms. First full analysis will be performed 6 months following trial closure and will be presented. Interim analysis performed on 285 patients (144 A and 141 S) showed consistently higher rates of