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C-267

CHEMO- VERSUS CHEMOIMMUNOTHERAPY IN ADVANCED BREAST CANCER
H. B. Muss, M. R. Cooper, F. Richards, II, D. R. White, and C. L. Spurr. Bowman Gray School of Medicine of Wake Forest University, Winston-Salem, N. C.

151 evaluable patients with advanced breast cancer have been prospectively randomized to one of four treatment regimens:

1) CDFVP; cyclophosphamide (C), 300 mg/M^2; doxorubicin (D) 20 mg/M^2 and Flourouracil (5-FU,F), 500 mg/M^2, all I.V. q 2 wk with vincristine (V) 1 mg/M^2, I.V. q 4 wk and prednisone (P) 5 mg p. o. twice daily;
2) CDFVP+MER is the same as 1 with the addition of the methanol extraction residue of BCG (MER) 100 mcg I.D. injected into 4 sites (400 mcg total) q 4 wks;
3) CD/MF; C-300 mg/M^2 I.V. and D-30 mg/M^2 I.V. on day 1 methotrexate (M) 25 mg/M^2 I.V. and 5-FU 600 mg/M^2 I.V. on day 14, repeated every 4 weeks;
4) CD/MF-MER is the same as 3 with the addition of MER I.D. q 4 wk in the same dose as in 2.

Patient accrual is almost complete. Disease free interval, menopausal status, and metastatic disease distribution are similar in the four groups. Preliminary response data are as follows:

REGIMEN	No.Pts.	CR No.(%)	PR No.(%)	STABLE No.(%)	PROGRES. No.(%)
1) CDFVP	39	4 (10)	17 (44)	9 (23)	9 (23)
2) CDFVP+MER	36	3 (8)	15 (42)	12 (33)	6 (17)
3) CD/MF	40	4 (10)	13 (32)	11 (28)	12 (30)
4) CD/MF+MER	36	2 (6)	12 (33)	15 (42)	7 (19)

Toxicity has been minimal. Response rates for all four groups are similar but median duration of CR+PR with CD/MF+MER may be significantly longer (73 wks) than with CDFVP (56) CDVPF+MER (59) or CD/MF (56). Immunotherapy with MER may prolong response duration in patients with metastatic breast cancer. (Partial support by NCI CA-12197)

C-269

COMBINATION CHEMOTHERAPY FOR NON-OAT CELL CARCINOMA OF THE LUNG: A RANDOMIZED STUDY.
Richard W. Opfell, M.D. and David Plotkin, M.D., St. Joseph Hospital, Orange, California 92668.

68 patients with advanced non-oat cell carcinoma of the lung were randomized to treatment with either CMF: (Cyclophosphamide 100mg/M^2 orally daily , days 1-14; Methotrexate 40mg/M^2 I.V. days 1 and 8; and, Fluorouracil 650mg/M^2 I.V. days 1 and 8. Cycles were repeated every 4 weeks) or CAMP (Cyclophosphamide 300mg/M^2 I.V. days 1 and 8, Adriamycin 20mg/M^2 I.V. days 1 and 8, Methotrexate 15mg/M^2 I.V. days 1 and 8, Procarbazine 100mg/M^2 orally daily days 1-10. Cycles were repeated every 4 weeks.) Doses were reduced by 25% in patients over 65 years of age. These patients have been treated since July, 1977 by community oncologists participating in the Oncology Network of Southern California. Patient characteristics included: median performance status (PS) of 70% (Karnofsky Scale), median age of 57.9, and prior treatment in 35, radiation in 29, radiation and chemotherapy in 2. One patient had a complete response (CR) and 12 have had partial response (PR). The one CR occurred in a patient with adenocarcinoma and PR was seen in 4/26 adenocarcinoma, 6/23 epidermoid carcinoma, 2/16 other, including large cell anaplastic carcinoma. Median survival from the start of treatment was five (5) months and actuarial survival curves were identical in the two treatment arms. Toxicity was mild to moderate. There were two allergic reactions. There were no drug related deaths. Nausea was more common in the CAMP patients frequently necessitating reductions in Procarbazine dosage. Median leucocyte count nadir was 4,000 and median platelet count nadir was 143,000. We conclude that CMF and CAMP are equally effective for therapy of non-oat cell carcinoma of the lung and can be administered with acceptable toxicity. We conclude that community oncologists can effectively participate in sophisticated clinical trials.

C-270

PHARMACOKINETIC STUDIES OF 5-FLUOROURACIL (5-FU) IN CANCER PATIENTS USING GC/MS AND HPLC METHODS.
J.P. Cano, Y. Carcassone, C. Aubert, J.P. Rigault, C. Luccioni, and Y.M. Rustum. Depts. of Pharmacokinetics, Faculty of Pharmacy, University of Marseille, France; and Experimental Therapeutics and Medicine A, Roswell Park Memorial Institute, Buffalo, New York 14263.

Pharmacokinetic studies of 5-FU were undertaken in man in an attempt to explain individual variations in toxicity and response. Two methods of analysis were used: 1) high pressure liquid chromatography (HPLC) using plasma extracted with ether-isopropanol (80:20) and chromatographed on a LiChrosorb Si 60 (5 µm) column with sensitivity of 50 ng/ml plasma at 264 nm, and 2) gas chromatography-mass spectrometry (GC/MS) of methylated compounds, with selective molecular ion monitoring and sensitivity to 5 ng/ml. 5 Bromouracil was used as an internal standard in both systems, which gave equivalent results. Pharmacokinetic studies were carried out in 8 patients with colon carcinoma receiving 5-FU (15 mg/kg) by i.v. push and one week later a continuous eight hour infusion of the same dose. Following intravenous administration of 5-FU the clearance of the drug scatters from 0.39 to 1.47 L/min. The clearance by continuous infusion in the same patients, however, ranged from 5.41 to 57.88 L/min. During the 8 hour infusion, the plasma levels of 5-FU in different patients ranged from 44 to 350 ng/ml. These data indicate a rapid decrease in plasma drug concentrations following an i.v. push of 5-FU and show a considerable variation in the plasma levels of 5-FU achieved and its clearance rate among different individuals during intravenous infusion. Because of these intra and intersubject variations, a model is being studied which predicts the kinetics of FU infusion from those of FU bolus in individual patients. Supported in part by INSERM, France; and USPHS Grant CA-21071.

C-271

IMPACT OF CHEMOHORMONAL THERAPY UPON MAINTENANCE IN ADVANCED BREAST CANCER.
D. Tormey, R. Gelman, P. Band, G. Falkson, Univ. Wis. Cancer Ctr., Madison, WI 53706; Sidney Farber Cancer Ctr., Boston, Mass 02115; Centre Hospitalier Notre-Dame, Montreal, CAN H21 4M1; H.F. Vorwoerd Hosp. S.A.; for the Eastern Cooperative Oncology Group.

119 evaluable pts were entered onto 3 Induction regimens across 2 protocols and, being in response at 6 months, were randomized to maintenance with: I-CMF (62 pts), II-CMF + fluoxymesterone (H)(57 pts). Induction regimens were CMF (23 pts), CMF + Prednisone (P)(54 pts), and AV (42 pts). CMFP and AV doses (mg/m^2): C-100 po d1-14; M-40 iv d 1,8; F-600 iv d 1,8; P-40 po d1-14; A-60 iv d1; V-1.2 iv d1. F dose: 10 mg po bid. CMF(P) cycles were 28d and AV cycles 21d. 8/84 (9.5%) partial responders (PR) converted to complete responses (CR) during maintenance. Median time to treatment failure (90/119 failures) and survival (67/119 failures) from start of maintenance was:

Induction Regimen	Mos to Failure (TTF) CMF	CMFH	P_{2t}	Survival (mos) CMF	CMFH	P_{2t}
AV	5.8	11.8	.08	13.1	19.1	>.10
CMF	2.8	6.6	.08	11.7	15.0	>.10
CMFP	6.7	12.5	.08	>37	>37	>.10
Total	5.9	11.1	.002	19.7	22.9	>.10

The effect of H was only in PR where TTF was 5.3 for CMF and 10.8 for CMFH (p=.003), and not in CR where TTF was 8.1 for CMF and 9.0 for CMFH (p>.10). % delivery of C, M and F per m^2 was 36-63% greater in the CMFH regimen by the 4th cycle, (p=.08,.001,.005, respectively). Hemoglobin on d1 of each cycle also became higher with CMFH by cycle 4 (p=.03). There was no difference in overall hemopoietic or gastroenteric toxicity or infections between the regimens. Addition of H to a maintenance CMF regimen appears to increase the therapeutic effect; the data suggests that this may be related to increased marrow support by H allowing greater drug delivery.