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C-267
CHEMOTHERAPY VERSUS CHEMIOIMMUNOTHERAPY IN ADVANCED BREAST CANCER
H. R. Vass, M. R. Cooper, P. Richards, J. D. R. White, and C. L. Sparr. 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) CEFVP: cyclophosphamide (C), 300 mg/m²; doxorubicin (D) 20 mg/m² and Fluorouracil (5-FU); 500 mg/m², all I.V. q 2 wk with vincristine (V) 1 mg/m², I.V. q 4 wk and prednisone (P) 5 mg p. o. twice daily;
2) CEFVP + HER is the same as 1 with the addition of the monoclonal anti-carcinoembryonic antigen (CEA) monoclonal antibody 100 mg I.D. injected into 4 sites (400 mcg total) q 4 ws;
3) CD/MF; C-300 mg/m² I.V. and D-30 mg/m² I.V. on day 1 methotrexate (M) 25 mg/m² I.V. and 5-FU 600 mg/m² I.V. on day 14, repeated every 4 weeks;
4) CD/MF + HER is the same as 3 with the addition of HER 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:

<table>
<thead>
<tr>
<th>REGIMEN</th>
<th>No. Pts.</th>
<th>CR</th>
<th>PR</th>
<th>No. (%)</th>
<th>No. (%)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEFVP</td>
<td>39</td>
<td>4</td>
<td>(10)</td>
<td>17 (44)</td>
<td>9 (23)</td>
<td>9 (23)</td>
</tr>
<tr>
<td>CEFVP + HER</td>
<td>36</td>
<td>3</td>
<td>(8)</td>
<td>15 (42)</td>
<td>12 (33)</td>
<td>6 (17)</td>
</tr>
<tr>
<td>CD/MF</td>
<td>40</td>
<td>4</td>
<td>(10)</td>
<td>13 (32)</td>
<td>11 (28)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>CD/MF + HER</td>
<td>36</td>
<td>2</td>
<td>(6)</td>
<td>12 (33)</td>
<td>16 (42)</td>
<td>7 (19)</td>
</tr>
</tbody>
</table>

Toxicity has been minimal. Response rates for all four groups are similar but median duration of CMF + HER and CD/MF + HER may be significantly longer (73 ws) than with CEFVP (56) CD/MF (59) or CD/MF (56). Immunotherapy with HER may prolong response duration in patients with metastatic breast cancer. (Partial support by NCI CA-12187)

C-269
COMBINATION CHEMOTHERAPY FOR NON-OAT CELL CARCINOMA OF THE LUNG: A RANDOMIZED STUDY. Richard W. Opfizer, 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/m² orally daily, days 1-4; Methotrexate 30mg/m² I.V. days 1 and 8; Fluorouracil 650mg/m² I.V. days 1 and 8. Cycles were repeated every 4 weeks) or CAMP (Cyclophosphamide 300mg/m² I.V. days 1 and 8; Adriamycin 20mg/m² I.V. days 1 and 8; Methotrexate 15mg/m² I.V. days 1 and 8; Procarbazine 100mg/m² 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 57.3, and poor treatment in 3%, radiation in 29, 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 4/16 adenocarcinoma, 6/23 epidermoid carcinoma, 2/16 others, including 1 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. Neutropenia was more common in the CAMP patients. Frequently necessitating reductions in Procarbazine dosage. Median leukocyte 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 EPLC METHODS. J. P. Cano, Y. Carcassonne, C. Aubert, J.P. Rigalut, C. Lucchioni, 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 extracts 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 scatter from 0.7 to 1.4 L/min. The clearance by continuous infusion in the same patients, however, ranged from 5.4 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 concentration. However, 5-FU bioavailability is lower than that obtained by i.v. push 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 this intrasubject and intersubject variations, a model is being studied which predicts the kinetics of FU infusion from those of FU bolus in individual patient. Supported in part by INSEM, France, and USAFS Grant CA-21071.

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119 evaluable pts were entered onto 3 induction regimens followed by maintenance therapy. Maintenance therapy at 6 months, were randomized to maintenance with: I-CMF (62 pts), II-CEF + fluoroxymesterone (H) (57 pts). Induction regimens were CEF (21 pts), CMF + prednisone (P) (54 pts), and AV (42 pts). CMF and AV doses (mg²): C-100 pg po dl-14; M-40 i.v 1 dl; F-800 pg po dl-14; P-400 pg po dl-14; A-60 pg iv dl; V-1.2 pg iv dl. F dose: 10 mg po bid. CMF(C) cycles were 28d and AV cycles 21d. 8/84 (9.5x) partial responders (PR) converted to complete responses (CR) during maintenance. Median time to disease failure (90/119 failures) and survival (67/119) failures from start of maintenance was:

<table>
<thead>
<tr>
<th>Induction</th>
<th>No to Failure (TF)</th>
<th>Survival (mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimen</td>
<td>CMF</td>
<td>CMF</td>
</tr>
<tr>
<td>AV</td>
<td>5.8</td>
<td>11.8</td>
</tr>
<tr>
<td>CMF</td>
<td>2.8</td>
<td>6.6</td>
</tr>
<tr>
<td>CAMP</td>
<td>6.7</td>
<td>12.5</td>
</tr>
<tr>
<td>NIP</td>
<td>1.9</td>
<td>8.0</td>
</tr>
</tbody>
</table>

The effect of H was only in PR where TF was 5.3 for CMF and 10.8 for CMF (p=0.003) and not in CR where TF was 8.1 for CMF and 9.0 for CMF (p=0.10). Z delivery of C, M and F per m² was 36-63% greater in the CMF regimen by the 4th cy- cle, (p=0.001,0.005 respectively). By hemoglobin on 1 4000 cells each cycle also became higher with CMF by cycle 4 (p=0.03).

There was no difference in overall hematopoietic 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 decreased narrow support by H allowing greater drug delivery.