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C-217

TREATMENT OF ADVANCED BREAST CANCER WITH MEDROXY-PROGESTERONE ACETATE.
A phase III evaluation of the dose-response relationship at two dose levels.

C.Rose,H.T.Mouridsen, E.Engelsman, M.Nooi, R.Sylvester, N.Rotmensz for the EORTC Breast Cancer Group, Finsen Institute, 49 Strandboulevarden, 2100 Copenhagen Ø, Denmark.

Medroxyprogesterone acetate (MPA) binds specifically to the progesterone receptor in the human mammary tumor cytosol, but it has also affinity for the glucocorticoid and the androgen receptors. It is therefore conceivable, that MPA given at high doses may affect mammary tumor growth by binding not only to progesterone, but also to the other two receptors. The EORTC Breast Cancer Group has therefore conducted a randomized dose-response trial comparing the contineous oral administration of 300 and 900 mg of MPA daily. Patients with advanced measurable cancer, clinically resistant to prior cytotoxic and/or endocrine therapy were eligible for the study.
Among 201 evaluable patients, the overall response rate was 23 and 16 % in patients treated at the high and low dose level, respectively (p=0.08). The time to progression was significantly longer in those treated with the high dose (p=0.02).Response duration and survival was insignificantly prolonged in those receiving high dose MPA.
The results indicate a dose response relationship for treatment with progestins.

C-218

STUDY OF HUMAN BREAST CANCER IN SOFT AGAR CULTURE
T. K. Banerjee, J. J. Marx, Jr., S. K. Spencer, B. J. Ault, Don Stoiber, S. M. Sajjad, Marshfield Clinic and Marshfield Medical Foundation, Marshfield, WI 54449. (Sponsored by T. K. Banerjee)

One hundred and forty three malignant samples (67 tissues and 76 fluids) from 101 women with breast cancer were subjected to human tumor clonogenic assay (HTCA). Eighteen samples were not plated because of insufficient tumor cells and 6 culture plates were contaminated with bacterial or fungal infection. Sixty three of 119 (53%) samples had adequate growth (≥30 colonies). Eleven samples had inadequate growth (<30 colonies). Twenty seven of 56 tissue samples (48%) had adequate growth and 6 had inadequate growth. Of these 56 samples 30 were taken from primary breast tumors and 26 were from metastatic sources. There were 53.3% (16/30) of primary sources and 46% (12/26) of metastatic sources that grew adequately. The pleural fluid samples grew 65% (30/46) and the ascitic samples 29% (5/17) adequately. Eleven of twenty two of estrogen receptor (ER) positive and 12/20 ER negative tissue specimens grew. It appeared that the colony numbers on an average was lower in ER positive tumors with ≥101 Fml/ng of protein values. The colony growths of 2 malignant fluids were confirmed as malignant tumor cells by electron microscopic examination. No correlation with histiologic grading and colony growth can be made. When receptor results were plotted against sensitivity to various hormonal agents there were a great deal of variations in individual samples. In 2 instances, even though the ER was negative there was wide range of sensitivity in the HTCA against various hormonal agents tested. HTCA results of 6 tissue and 18 fluid samples were evaluated clinically. Twenty three percent of those shown to be sensitive, responded to the indicated drug and 77% thought to be resistant actually were.

C-219

PROSPECTIVE COMPARISON OF COMBINATION CHEMOTHERAPY WITH OR WITHOUT A PROSTAGLANDIN SYNTHESIS INHIBITOR IN ADVANCED BREAST CANCER.
A. Khojasteh, R.D. Reynolds, A.R. Garcia, E.P. Mitchell, J. Walter, N.O. Anson. Ellis Fischel Cancer Center, Columbia, Missouri 65203.

The safety and efficacy of mitomycin-C (MTC) and continuously infused vinblastine (VLB) therapy in metastatic breast cancer have previously been demonstrated. The ability of prostaglandin synthesis inhibitors (PSI) to reduce growth of mammary carcinoma has recently been described in experimental and clinical settings. An ongoing phase III trial has been conducted to determine the impact of a PSI (ibuprofen) on the response of advanced breast carcinoma (BC) to a combined chemotherapy (VLB + MTC) regimen. At the time of this evaluation 13 pretreated females with measurable BC (age range: 29 to 64 years; 2 premenopausal, 11 postmenopausal) have entered in this study. 7 patients received VLB (1.5 mg/m^2 I.V. over 24 hours on days 1-5) + MTC (10 mg/m^2 I.V. on day 3) every five weeks. 6 patients were treated with aforementioned chemotherapy plus ibuprofen (1800 mg, p.o. daily). Both treatment groups were comparable in age, menopausal and hormonal receptor status and number of courses of therapy. The treatment was well tolerated by most patients. The overall partial response following 2 to 8 courses of the therapy was observed in 5/13 patients. Stabilization of measurable lesions for 10 to 37 weeks was noted in 3/13 patients. The remaining patients (5/13) failed to respond. The preliminary results suggest that, in the limited number of studied cases, ibuprofen at the current dose schedule does not contribute to the improvement of response rate to chemotherapy. More extensive trails of the PSI combined with chemotherapy regimens, with specific reference to incidence of osseous metastasis, bone pain, hypercalcemia and therapeutic index of antineoplastic agents in connection with chemotherapy related mucosal damage, are in process.

C-220*

ADJUVANT TREATMENT WITH TAMOXIFEN IN POSTMENOPAUSAL PATIENTS WITH HIGH RISK BREAST CANCER: 78 MONTHS OF LIFE TABLE ANALYSIS.
H.T. Mouridsen, C. Rose, S.M. Thorpe, J. Andersen, M. Blichert-Toft, and K.W. Andersen for the Danish Breast Cancer Cooperative Group (DBCG), Finsen Institute, 49 Strandboulevarden, 2100 Copenhagen Ø, Denmark.

This nationwide trial included postmenopausal (e.g. 5 years of menostasia) patients less than 80 years of age with primary high risk (e.g. node positive) breast cancer. Primary treatment was total mastectomy and axillary sampling followed by radiotherapy (RT) to the scar and regional lymphnodes. From august 1977 to november 1982 1650 patients entered the trial: 821 were randomized to no further therapy (RT-group) and 829 to treatment for 1 year with tamoxifen 30 mg daily (RT+TAM-group).

At 6 years life table analysis the recurrence free survival (RFS) is 44% in the RT+TAM-group and 40% in the RT-group (p=0.0003). Survival is identical (51%) in the two groups (p=0.53). The data have been further analysed in relation to prognostic factors e.g. age, degree of anaplasia, tumor size and number of positive nodes. The RFS is lower in all subsets of patients treated with RT + TAM, but the difference is statistically significant only in patients 50-59 years of age, with tumors of grade I, or with 4 or more positive lymphnodes.

Estrogenreceptor (ER) concentration were measured in a subset of 292 of the patients. A cut-off limit of 10 fmol/mg cytosol protein significantly distinguishes between patients with long RFS and those with early recurrent disease. Patients with ER content below 100 fmol/mg did not benefit from the endocrine therapy why those with concentrations above 100 fmol/mg had a significantly longer RFS. 198 of the patients had progesterone receptor (PgR) determinations and the PgR positive patients treated with TAM did significantly better than the control group (p=0.015).

Evaluation of the clinical results as of April 1985 will be presented.

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