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TAMOXIFENE AND HIGH DOSE OF MEGESTROL ACETATE IN SEQUENTIAL ALTERNATE THERAPY IN ADVANCED BREAST CANCER.

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From January 1992 to September 1993, 45 women afflicted by advanced breast cancer received an alternate treatment shaped by Tamoxifen: 20mg/die for 14 days and then Megestrol Acetate 160mg/die p.o. for 14 days, followed a period of 7 days of wash-out and then another treatment TAM/MA. All the patients, with a median age of 64-69 year at the time of the diagnosis was been treated with a polychemotherapy CMF (1-21) for 6 cycles. They never received hormone therapy and they had a positive receptorial condition for the estrogen with or without progesterone; the lesions was objectively valuable. To the follow-up of 24 months has been observed a RP sup 50% and an improvement of the general condition

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VELF: an active outpatient regimen for aggressive metastatic breast cancer (MBC). Preliminary results.

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Seventeen consecutive pts with MBC were treated with: VINORELBINE: 25 mg/m² iv day 1, 8, 15; EPIRUBICIN: 100 mg/m² iv day 1; 5-FLUOROURACIL:

400 mg/m² iv day 1 to 3, repeated every 21 days. G-CSF 300 µg s.c. was administered on every day without chemotherapy (CT). Fourteen pts are fully evaluable (three too early). Median age: 45 yrs (26-55), ECOG PS: 1 (0-2), ten had prior adjuvant CT. Thirteen had visceral metastases and one locally advanced carcinoma with skin metastases. ER were negative in 5 pts and positive in six. 69 Cycles have been given (median 5/pt, range 2-6). Four CR and 6 PR were obtained (RR=71%), 4 pts had stable disease. TTF is 6+ mos (2-9+) and OS 11+ mos (2+ -18), respectively. Seven pts experienced grade IV and 3 grade III neutropenia (no grade > 1 on day 21), one grade IV and 2 grade III thrombocytopenia occurred (no grade > 0 on day 21). Grade III mucositis and diarrhea were seen in 3 and 1 pts, respectively. Six pts were admitted to the hospital (three neutropenic fever, two severe phlebitis and one paralytic ileus). Alopecia was universal. This regimen has substantial activity with reasonable toxicity in this selected group of pts with mainly visceral MBC. Dosage escalation of Epirubicin and 5-Fluorouracil is ongoing.

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TUMOR CELL DETECTION IN BONE MARROW OF PRIMARY BREAST CANCER PATIENT

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At the Department of Obstetrics and Gynecology, University Erlangen, a prospective trial was carried out concerning the prognostic value of tumor cell detection in bone marrow using monoclonal antibodies against EMA with respect to the probability of tumor recurrence and the duration of disease free survival.

Bone marrow punctions were taken from 280 patients with primary breast cancer and then immunocytochemically analysed for tumor cells.

136 of the 280 patients were tumor cell positive. 76 patients developed recurrences.

56 of the 76 patients had positive bone marrow punctions.

Positive bone marrow punctions also showed a strong correlation to the probability of bone metastasis development.

The number of recurrences and the disease free survival in EMA - positive patients was significantly higher and shorter respectively than that of EMA - negative patients.

A multivariate analysis of the results demonstrated that bone marrow puncture is independent of other established prognostic criteria.

According to our results tumor cell detection in bone marrow is an important and independent prognostic factor in breast cancer.

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METHOTREXATE, MITOXANTRONE, FLUOROURACIL AND LEUCOVORIN (MMFL) IN METASTATIC BREAST CANCER PATIENTS (PTS).

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We have evaluated the efficacy and toxicity of a chemotherapy consisting of methotrexate 200 mg/sqm d 1, Mitoxantrone 10 mg/sqm d 1, fluorouracil 600 mg/sqm and Leucovorin 500 mg/sqm d 2 q 21-28 in 21 pts. 10/21 pts were pretreated with anthracyclines; the sites of metastases were: soft tissue 9 pts, bone 14 pts, viscera 13 pts. A total number of 108 courses were administered with a median number of 6 (range 1-12). Among 20 evaluable pts, objective response was obtained in 6 pts (30%) with 2 complete responses (lung, soft tissue), stable disease in 4 pts (20%), while 10 pts (50%) progressed. Median progression free survival and survival were 10 and 15 months respectively.

The most frequently observed side effects were myelosuppression and emesis; 1 pt, who prior received doxorubicin at the maximum dose-limiting cardiac toxicity, died of congestive heart failure after third cycle.

This treatment is moderately effective for advanced breast cancer pts.

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PHASE II STUDY OF EPIRUBICIN (EPI) AND LONIDAMINE (LND) IN ADVANCED BREAST CANCER

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The aim of this study is to value the activity and the toxicity of combination LND and EPI in advanced breast cancer. Treatment: EPI 75 mg/mq iv every 21 days and LND 450 mg/d orally from day 1 continuously. 33 patients (pts) are entered into the study and 30 pts were evaluable for response at 6 course. This combination induced 12 RO (4 RC + 8 RP) (40%), 6 NC (20%), 12 P (40%).

The median duration of the response was 9 months (1 - 19). All the pts were evaluable for toxicity. The most frequent side effects were nausea and vomiting, leucopenia, alopecia, myalgias. The RO rate (40%) is quite similar to that expected from EPI alone, but the median duration of RO and NC is encouraging and it suggests that LND has more influence on the duration of RO and NC than on the response rate.

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SURFACE ELECTRICAL POTENTIALS AS BIOPHYSICAL INDEX OF PROLIFERATIVE DISEASES: APPLICATIONS TO BREAST CANCER DIAGNOSIS.

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Electrical depolarisation accompanies upregulated proliferation of neoplastic growth. This phenomena can be detected at the skin surface and analyzed for direct current (dc) potential differences in diagnosing breast carcinoma. Previous US studies indicate a sensitivity of 97% and a specificity of 79%. In order to verify this diagnostic accuracy the Istituto Nazionale Tumori has participated in a validation study, supported by Biofield Corp. of New York, with the aim of standardizing the technique before implementing a controlled blinded multicentric study. The test is based on measurements of dc potentials from several breast electrodes relative to reference electrodes on the palms. Only patients scheduled for open biopsy are tested. Potential differences within the symptomatic breast and between each breast are used for diagnosing a lesion. The analysis of tests are done independently from the pathological outcomes, which are compared to the Biofield diagnosis. Analysis of the first 218 consecutive cases indicate that cancers (n=132) produce significantly greater dc potential differences than benign lesions (n=86; p<0.05). Sensitivity was found to be 97% and specificity was found to be 85%. The size of the lesion (34% <= 1 cm), age of patient (46% <50 years) and previous breast irradiation for conservative breast surgery did not affect diagnostic accuracy.