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CLINICAL RELEVANCE OF CA 15-3 IN COMPARISON TO OTHER TUMOR MARKERS IN DIAGNOSIS AND FOLLOW UP OBSERVATIONS OF BREAST CANCER PATIENTS

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The Centocor Ca 15-3 is a new in vitro test system for breast cancer patients utilizing two monoclonal antibodies which react with circulating antigen expressed by human breast carcinoma cells. Normal control persons demonstrated plasma values below 30 U/ml (median 14 U/ml). Pregnant women were found to have elevated levels 30-60 U/ml in 11,5% (3/20) of the cases, whereas in the amniotic fluid only normal values were measured. In patients with ovarian cancer we observed in 9/12 (75%) cases in part extremely high (>700 U/ml) plasma oncentrations of Ca 15-3. Breast cancer patients with localized tumors without distant metastases demonstrated Ca 15-3 plasma levels above 30 U/ml in nearly 30%. There was no correlation to tumor size or axillary lymphnode involvement. Cases with a dissemination of the disease showed increased plasma values in 65% (partly ≥500 U/ml). The plasma level seemed to be influenced by the extent and the localisation of the metastases. Raising Ca 15-3 plasma concentrations could be found a few months before clinical diagnosis of new metastases. Follow-up examinations of Ca 15-3 positive patients showed a good correlation between the clinical course and this tumormarker. A comparison of Ca 15-3 with established markers as CEA and TPA will be demonstrated. In conclusion our present results indicate that Ca 15-3 can give further information in monitoring breast cancer patients.

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CA 15-3, A SPECIFIC TUMOUR MARKER FOR BREAST CANCER?

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CA 15-3 is supposed to be a circulating antigen expressed by human breast tumour cells. It can be detected by an available RIA-kit (Centocor), using 2 monoclonal antibodies against milk-fat globulin membranes (115 D 8) and a membrane-enriched fraction of human breast tumour tissue (DF 3). CA 15-3 plasma levels should serve as indicator and prognosis parameter for the follow-up for breast cancer patients.
To prove its validity we compared CA 15-3 plasma concentrations to CEA, TPA, CA 19-9 and CA 12-5 in the following test groups:

a) breast tumours of unknown dignity pre-operatively,
b) breast cancers in post-operative follow-up,
c) metastatic breast cancers in treatment follow-up,
d) other gynecologic cancer patients,
e) breast-feeding patients and
f) a control group with non-carcinomatous gynecologic diseases.

Up to Oct. 31, 1985, a number of 498 patients have been examined. Preliminary results show that only a small number (about 1/3) of breast cancer patients show "positive" CA 15-3 levels before first treatment compared to the control group.
In post-operative follow-up, CA 15-3 seems to be a good indicator for metastatic disease ("positive" levels in about 3/4 of the patients). The concentration of CA 15-3 seems to be dependant upon the tumour load. There were no "positive" CA 15-3 values in the breast-feeding group, instead, most of these patients showed positive TPA and CA 12-5 values. The investigations are in progress.

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SIGNIFICANCE OF TUMOR MARKERS, DETECTED WITH MONOCLONAL ANTIBODIES IN PATIENTS WITH BREAST CANCER

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Introduction: The significance of serum tumor markers in patients with malignant diseases has been controversial for many years. Low specifity and sensitivity seemed to conteract the advantage of a noninvasive, easily practicable method for routine follow up. The recent introduction of monoclonal antibodies for the detection of tumor associated antigens seems to be an important improvement for the monitoring of tumor behaviour. In a retrospective study, the sensitivity and clinical value of various tumor markers was investigated.
Patients and Methods: Blood samples of patients, who were admitted to the Department of Gynecologic Oncology, University Hospital Frankfurt/M between 1983 and 1985 for treatment or follow up of primary or advanced breast cancer, were taken for CEA analysis (EIA). Serum was frozen and stored at -20°C. In 1985 these samples were defrosted and testing of various tumor markers was performed. Each assay was performed in triplicates: CEA (IRMA), CA 15-3, CA 50, CA125, TPA. The results were compared and correlated with the clinical data.
Results: 1: Test results of the two CEA assays before and after storage were comparable. 2: CA 50 and CA 15-3 were less sensitive than CEA. In 30 patients with advanced breast cancer and positive CEA values, only 17 cases showed elevated levels for CA 50 and CA 15-3. Among 30 patients with normal CEA levels, raised serum values of CA 50 and CA 15-3 in 6 respectively 9 patients could be demonstrated. 3: No correlation could be found between the extent of the disease and the level of tumor markers. 4: CA 125, a tumor marker reported to be specific for epithelial ovarian cancer (R.C.Bast et al, N Engl J Med 309(1983),883-887), was found elevated in several patients with breast cancer.
Conclusions: In this study, CA 50 and CA 15-3 failed to demonstrate a higher specifity and sensitivity than CEA. In the future it will be more important, to investigate the expression of the various markers in tumor tissue. This might be a reliable basis for the monitoring of tumor markers in the patients serum (Isaacson et al, Gut 18(1977)779)

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Bre 34

NEO-ADJUVANT CHEMOTHERAPY OF BREAST CANCER STAGES T3/4 , N± ,Mo.Prospectively randomized clinical trial: Zytotoxic chemo- + hormonal therapy(CMF.Vincr.Mitox. + Tam.) vs. radiotherapy.H.Rainer et al.,Arbeitskr. f. perioperat. Chemotherapie,Austria.:

Work on pre-operative clinical studies in breast cancer stages T3/4,N -/+,Mo,was started in 1983 with a prospectively randomized clinical trial comparing peri-operartive chemotherapy with peri - operative radiotherapy.Initially patients were assigned to receive either chemo- or radiotherapy.Patients of the chemotherapy group were treated by 2 cycles of chemotherapy pre- operatively.After definitive surgery patients were classified as responders or non-responders by the intraoperative findings of the radiologist ,surgeon or pathologist.Sofar 92 patients were randomized.Mean observation period was 328±205 days.82±53 days after study enrollement patients were definitively operated by (modified)radical mastectomy.In the chemotherapy subgroup 2/28(7%) achieved CR , 10 / 28(36%) PR, 10/28(36%) IMP, 3/28 (11%) NC , 1/28(4%) progression and 2/28(7) were not evaluable.Radiotherapy resulted in similar response rates.Chemotherapy was well tolerated despite a 6 drug combination therapy. In 113/152 cycles no nausea or vomiting was noted(74 %) and in 120/152(79%) no hair loss.Mean dosages in % of a theoretical scheme for the pre-operative period were as follows : Methotrexate 103±40%, Vincristine 103±40%,Fluorouracil 103 ± 63% , cyclophosph.103±400%,Mitoxantrone 97±44% and tamoxifen 96±19%.Mean tumor shrinkage of primary by chemotherapy was 37% , by radiotherapy 35%.The main purpose of this study is to establish a rational basis for postoperative cytotoxic treatment excluding nonresponders from unnecessary postoperative drug-administration.