consisted of two consecutive phases: a double-blind placebo controlled phase of 14 days (phase A) and an open phase of 76 days (phase B). During phase A patients were treated with MA 2 tablets × 160 mg/day (a low dose for this indication) or placebo. In phase B all patients received different dosages of MA according to the response to treatment.

A patient was considered responsive if his appetite, evaluated by means of a categoric-numeric scale, increased by 2 or more points.

Other parameters investigated were: food intake, body weight, Performance Status (Karnofsky), mood state (POMS) and pain.

Results: Forty-two patients were enrolled in this trial. Thirty-three patients were evaluable for efficacy: 13/16 MA patients were responsive for appetite vs 5/17 placebo patients. This result is clinically and statistically significant ($P < 0.003$). No relevant toxicity occurred during the study.

Conclusions: MA showed a remarkable effect on appetite with a low dose (2 tablets × 160 mg/die) already after 14 days, without side-effects of relief.

This result is of great importance considering the relevance of the quality of life and the low life expectancy of these patients and the low daily therapy costs of this treatment.

Tumour markers

1254 ORAL

PREDICTIVITY OF CIRCULATING TUMOR MARKERS (CEA, MCA, CA 15.3, CA 549) IN BREAST CANCER RECURRENCE AFTER SURGERY

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Concomitant measurement of 4 serum markers (CEA, MCA, CA 15.3 and CA 549) were performed every 3–6 months in 128 breast cancer patients with no evidence of disease after surgery. After a median follow-up of 4 yrs (range 3–4 yrs) 29 pts (23%) relapsed. In 24 of these at least one marker was abnormal (sensitivity: 83%); the 5 pts with normal marker value at the time of relapse had only local recurrence (soft tissue metastases). The sensitivity of CEA and MCA (33% and 47%) was significantly lower than the sensitivity of CA 15.3 (79%) and CA 549 (80%) ($P = .02$). Ninety-nine pts did not relapse: 90 have normal marker values (specificity: 91%). The predictive value of a positive test and of a negative test is 73% and 95%, respectively. The combination of 2 or more markers does not increase the sensitivity ($P = .7$) and the positive predictive value of the test when compared to CA 15.3 or CA 549 alone. In conclusion a single marker determination (CA 15.3 or CA 549) is recommended in the follow-up of pts after surgery for breast cancer.

1255 ORAL

CEA, CA 15-3 AND MCA: COMPARATIVE CLINICAL RELEVANCE IN BREAST CANCER

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To comparatively investigate the clinical relevance of the serum tumor markers CEA, CA 15-3 and MCA simultaneous determinations of the serum concentrations of the three tumor markers CEA, CA 15-3 and MCA were performed in 419 sequential breast cancer patients. CEA and MCA were determined by means of enzyme-immuno-assays and CA 15-3 by a radio-immuno-assay.

Results: The serum concentration of all three tumor markers correlates with tumor activity and tumor mass. The receiver operating characteristics (ROC) curves show that CA 15-3 has the highest sensitivity and specificity. All three tumor markers do not show any dependence on age, but on the location of metastases; the median serum values decrease in the sequence osseous, visceral or soft tissue metastases. With a combination of tumor markers, the gain in sensitivity is associated with a loss of specificity; the combination of CA 15 + CEA appears to be the most favourable.

The combination of all three tumor markers does not have any advantage over the double combination CA 15-3 + CEA.

Conclusion: CA 15-3 has the highest sensitivity and specificity. As combinations of tumor markers CA 15-3 + CEA as well as MCA + CEA are recommended.

1256 ORAL

SERUM CYFRA 21-1 AS A PROGNOSTIC MARKER IN LUNG CANCER

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An immuno-radiometric assay was used to detect a fragment of the cytokeratin 19, referred to as CYFRA 21-1, in the serum of 405 patients with histologically proven lung cancer (314 non-small cell and 91 small cell lung cancers). This prospective study was conducted to evaluate the reliability of this immuno-radiometric assay, and to identify the relationship between serum CYFRA 21-1 and different features of lung cancer including prognosis. The reliability of the immuno-radiometric assay was demonstrated by the reproducibility of the dosage in intra-assay and inter-assay and the high sensitivity of the method in discriminating low CYFRA 21-1 concentrations. Using a threshold of 3.6 ng/mL, specificity was 0.96, and sensitivity was 0.55 and 0.36 for NSCLC and SCLC respectively. The sensitivity of the marker was highest in squamous cell carcinoma and lowest in small cell carcinoma. In non-small cell lung cancer patients, the marker varied significantly according to both stage of the disease, nodal status, weight loss, and performance status. A high serum CYFRA 21-1 level was strongly associated with advanced stages, mediastinal lymph nodes and poor performance status. NSCLC with serum CYFRA 21-1 over 3.6 ng/mL proved to have a significantly shorter overall survival than those with a normal serum level (log rank: $P = 0.0001$). A similar negative effect of a high serum CYFRA 21-1 on SCLC survival was found (log rank: $P = 0.004$). In Cox's model, performance status, stage grouping, lactate deshydrogenase and CYFRA 21-1 were significant determinants of survival.

1257 ORAL

TUMOR MARKERS AS PROGNOSTIC FACTORS FOR NON-SMALL-CELL LUNG CANCER (NSCLC)

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The prognostic value of CEA, SCCA, NSE, and LDH in 300 patients who had been irradiated for primary NSCLC was analysed retrospectively with univariate (Kaplan-Meyer, log-rank) and multivariate tests (Cox regression analysis).

Serum levels of the particular tumor markers were pathologically elevated in 25–36.5% of cases. Their values correlated with the stage of the disease. A normalization of increased marker levels 3 months after irradiation occurred in 37.5–67% of cases.

In univariate analysis survival with elevated CEA, SCCA, and LDH was significantly worse compared to normal levels. Normalisation after therapy was prognostically favourable.

In multivariate analysis the influence of tumor markers was meaningless. Independent factors were Karnofsky performance status, total dose, UICC-stage, and pretherapeutic weight-loss.