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# **PROGNOSTIC SIGNIFICANCE OF CA 15-3 IN BREAST CANCER PATIENTS**

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Eighty-six breast cancer pts were tested for serum CA 15-3 and followed for a period of two years. Cut off value for CA 15-3 serum level was set as 35 units/ml. In 28 pts with metastatic disease, mean CA 15-3 serum concentration (176 units/ml) and positivity rate (68%) were significantly higher compared to CA 15-3 mean serum level and positivity rate in 58 pts with no evidence of disease (18 units/ml and 3%). Actuarial 2-year survival curves were calculated according to CA 15-3 serum level. 93% of the pts with CA 15-3 level lower than 35 units/ml survived after two years, as compared to 56% of the pts with CA 15-3 between 35-100 units/ml and 5% of the patients with CA 15-3 higher than 100 units/ml ( $p < 0.05$ ,  $p < 0.001$  respectively). CA 15-3 serum level is a prognostic marker for prediction of 2-year survival.

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**EPITHELIAL OVARIAN CANCER (EOC): RATIONAL INTERVENTION USING TUMOUR MARKERS.** L. Finken, R.C.F. Leonard, J.E. Roulston - CRC Clinical Trials Centre, London, ICRF Medical Oncology Unit, and Royal Infirmary, Edinburgh, UK.

We have been monitoring EOC with CA125 and investigating alternative markers for nearly 10 years. Over 100 putative markers have been reported and the search continues for the ideal marker or panel. Only one, CA125, has established clinical value. However, its precise value is unclear. What role does CA125 play in screening? As a single screening test it is useless. Combined with transvaginal ultrasound in high risk women it may have sufficient predictive powers (PPV=30%). CA125 assay has become routine in many centres, but its impact on patient outcome has not been assessed. Clinicians accept CA125 in disease monitoring but not in prediction of relapse perhaps because they confuse it with "screening" and therefore underrate its value. We can challenge this conservatism: (i) monitoring relapse is equivalent to screening a population with a disease prevalence of about 50%; (ii) PPV, in this situation, is of the same order as sensitivity and specificity - about 85%; (iii) we have demonstrated the prognostic value of early CA125 assay; (iv) we know that HCG works in a group of post-hydatidiform mole women where the prevalence of choriocarcinoma is about 10%; and (v) the current approach to management has achieved nothing in 20 years. Initiation of two of the largest multicentre trials, ICON 1 and 2, provide the ideal opportunity to prospectively determine the clinical impact of CA125 measurement. Given the above reasons, it would be unethical not to take this opportunity to prospectively evaluate CA125.

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# **THE DIAGNOSTIC VALUE OF THE IMMUNOCYTOCHEMICAL DETECTION OF P53 PROTEIN AND SIALOSYL-TN-ANTIGEN IN SEROUS EFFUSION SPECIMENS**

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The distinction between cells of malignant mesothelioma (MM), metastatic adenocarcinoma (AC) and reactive mesothelial hyperplasia (MH) can often be a diagnostic problem. P53 protein is a valuable marker of malignancy and sialosyl-Tn-Antigen (STnA) expressed by a high proportion of carcinoma cells, is absent from normal and neoplastic mesothelial cells. Cell block sections from 30 effusion specimens (10 MM, 10 AC and 10 MH) were tested using two monoclonal antibodies (MAb) against P53 protein and STnA respectively, in a streptavidin-biotin-peroxidase immunostaining procedure. Results were as follows: P53 positivity in 8/10 MM, 9/10 AC and 0/10 MH; STnA positivity in 0/10 MM, 10/10 AC and 0/10 MH. The combined use of these two MAbs alone appears to be a helpful ancillary tool in the differential diagnosis of serous effusions exhibiting equivocal cytological appearances.

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# **ASSESSMENT OF TPS IN BREAST CANCER DURING PALLIATIVE AND ADJUVANT CHEMOTHERAPY**

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TPS is a new tumor marker that gives a quantitative indication of tumor cell proliferation activity. This test could have the potential to be a valuable tool for evaluation of tumor progress in breast cancer during chemotherapy. TPS is analyzed by an immunoradioassay using a monoclonal antibody against the M3-epitope of TPA. The normal range is 55 U/l at 95 % cut off. In this on-going prospective study we have now included 37 breast cancer patients, 22 (median age 55 years, range 46-74) for palliative and 15 (median age 46 years, range 28-50) for adjuvant chemotherapy. TPS is analyzed every and every third month, respectively. Median follow-up time is eight months. In the adjuvant group, TPS indicates advanced or progressive disease (PD) in 3/15 pts which so far is not confirmed by the traditional work up. In the palliative group so far seven pts with partial response (PR) and six with PD at the clinical evaluation is in accordance with the TPS analyzes. In three patients with stable disease the conclusions are still inconclusive. Two pts have shown a good correlation both during PD and PR. The preliminary impression is that TPS is of considerable value for monitoring chemotherapy in breast cancer patients. The time relationship has to be established more exactly.

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# **THE DIAGNOSTIC SENSITIVITY OF NEURON SPECIFIC ENOLASE (NSE) COMPARED TO OTHER TUMOR MARKERS (T.M.) IN FOLLOW UP OF ADVANCED DIGESTIVE CANCERS**

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NSE increased serum levels in patients with liver metastases of different digestive cancers were compared with other TM serum levels by diagnostic sensitivity. NSE, CEA, CA19-9 and CA72-4 were determined by IRMA CIS. After endoscopy and laparotomy the final diagnoses were concluded by microscopic findings. The cut off values in control group (50) were: NSE 10.3 ug/l, CEA 8.2 ng/ml, CA19-9 33.6 U/ml, CA72-4 2.7 U/ml. Diagnostic sensitivities of TM (ROC analysis): in colorectal adenocarcinomas with liver metastases (LM) (57): NSE 49.1% (28), CEA 77.2% (44), CA19-9 73.7% (42), CA72-4 45.6% (26); in stomach adenocarcinomas LM (10): NSE 40% (4), CEA 60% (6), CA19-9 60% (6), CA72-4 80% (8); in gall bladder adenocarcinomas LM (17): NSE 58.8% (10), CEA 88.2% (15), CA19-9 88.2% (15), CA72-4 88.2% (15); in pancreatic adenocarcinomas LM (15): NSE 80% (12),  $34.6 \pm 27.3$  ug/l ( $p < 0.01$ ), CEA 73.3% (11), CA19-9 93.3% (14) & CA72-4 46.7% (7). The NSE sensitivities were low than CEA and CA19-9, but increased NSE serum levels in pts. with liver metastases of pancreatic cancer suggest that NSE can be an accurate method for monitoring predicting outcome in pts. with advanced adenocarcinomas of digestive tract.

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# **THE ROLE OF HUMAN CHORIONIC GONADOTROPIN (HCG) ELEVATION IN SMALL CELL LUNG CANCER PATIENTS.**

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Elevated HCG-beta-subunit serum level (sbHCG) is found rarely in lung cancer, mostly in adenocarcinoma, but occasionally also in small cell lung cancer (SCLC). The significance of this finding is not known. The aim of the study was to assess the possible prognostic role of sbHCG in SCLC. sbHCG was measured with immunoassay (Abbott EIA sbHCG 15-15) in 186 SCLC patients (pts), 115 men and 71 women, median age 59 years. In 100 pts sbHCG was below 2 mIU/ml (group A), in 60 pts sbHCG was 2-5 mIU/ml (group B) and in 25 pts it was above 5 mIU/ml (group C). All the pts were treated with cytotoxic regimens. 54% of pts in the group C and only 24% and 30% of pts in the groups A and B did not respond to cytotoxic treatment (NR). The difference was statistically significant. After 18 months of follow-up 26% of pts in the group A, 30% of pts in the group B and only 13% of pts in the group C were alive. According to presented data, sbHCG above 5 mIU/ml seems to be a bad prognostic factor in SCLC.