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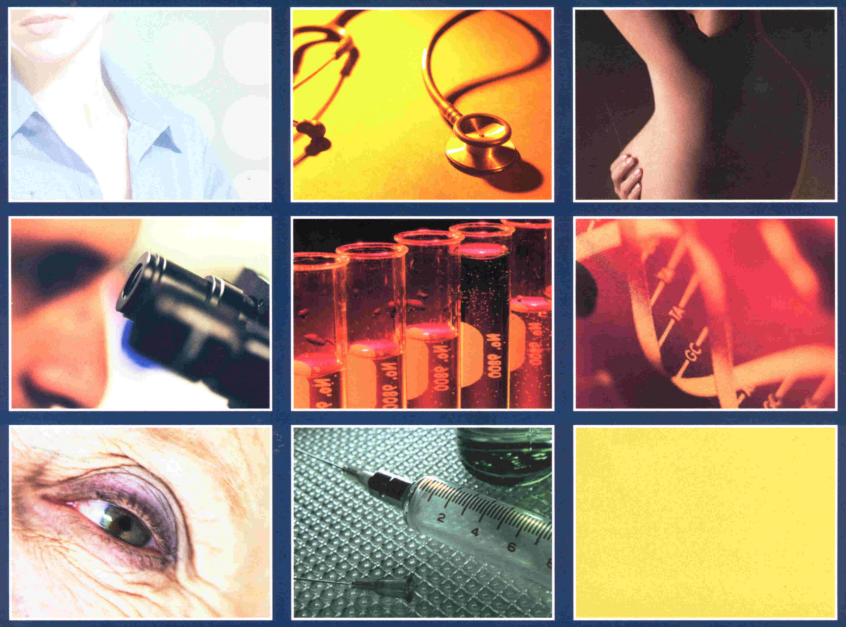

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Circulating epithelial tumor cells a new tool for therapy monitoring in breast cancer: a more than tenfold increase in numbers during systemic therapy is highly predictive of relapse.

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Background: To demonstrate the feasibility of the analysis of circulating epithelial tumor cells (CETC) to monitor the response to adjuvant therapy and to early detect patients at risk of relapse.

Patients and Methods: In 91 non-metastatic primary breast cancer patients CETC were quantified using Laser Scanning cytometry of anti-EpCAM stained epithelial cells from whole unseparated blood before and during adjuvant chemotherapy consisting of adjuvant Epirubicin/ Cyclophosphamid, Fluorouracil/Epirubicin/Cyclophosphamid with or without subsequent taxane, or Cyclophosphamid/ Methotrexate/ Fluorouracil therapy.

Results: Numbers of CETC were analyzed before each new cycle and at the end of chemotherapy. 3 typical patterns of response were observed: 1. a decline, 2. minor changes in cell numbers, 3. a (sometimes saw-toothed) increase (more than tenfold), or an initial decline with subsequent reincrease more than tenfold in numbers of CETC. 20 (22%) relapses were observed within the accrual time of 40 months, 1 among the 28 patients from response group 1; 5 among the 30 patients from response group 2 and 14 among the 33 patients from response group 3. Mean relapse free survival time was 537 days for patients without increase of CETC and 479 days for patients with increase of CETC. The difference in relapse free survival was highly significant ($p < 0.0001$).

Conclusion: These results show that cell numbers are influenced differently by the different agents and even after initial response to therapy, an increase at the end of therapy is a strong predictor of relapse (hazard ratio = 250) and is a surrogate marker for the aggressiveness of the tumor cells.