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BREAST CANCER

## Axillary lymph node nanometastases are prognostic factors for metastatic relapse in breast cancer patients

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Abstract

610

**Background:** Early breast cancer presents with a remarkable and largely unaccounted for heterogeneity of outcomes. Undetected, microscopic lymph node tumor deposits may account for a significant fraction of this prognostic diversity. Thus, we systematically evaluated the presence of lymph node tumor cell deposits <0.2 mm in diameter [pN0(i+), nanometastases], and analysed their

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prognostic impact. **Methods:** Seven hundred and two single institution, consecutive patients with 8 years of median follow-up were studied. To maximize the chances of detecting micro and nanometastases, whole-axilla dissections were analysed. pN0 cases were systematically reevaluated by step sectioning and anti-cytokeratin immunohistochemical analysis of 6676 corresponding dissected lymph nodes. The risk of first adverse events and of distant relapse of bona fide pN0 patients was compared with that of pN0(i+), pN1mi and pN1 cases. Crude cumulative incidence (CCI) curves were used to estimate the cumulative probability of occurrence of adverse events. CCI curves were compared by the Gray's test. A proportional sub distribution hazard (SDH) regression model was utilized to assess the difference among CCI curves of pN0(i+) versus pN0(i-), and of pN1mi versus pN0(i+). Competing risks were accounted for and regression models were adjusted for established breast cancer prognostic factors, i.e. grading, pathological T stage and age. Proportional SDH assumptions were checked using Schoenfeld-type residuals. **Results:** A pN0(i+) status was shown to be a strong risk factor for event-free survival ( $P < 0.0005$ ) and for metastatic relapse in both univariate and multivariate analyses accounting for competing risks and adjusted for grading, pathological T stage and age. **Conclusions:** Our findings demonstrate that nanometastases are an important risk factor in breast cancer. These results support the inclusion of procedures for nanometastasis detection in TNM pathological staging.

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