

## Circulating tumor cells as predictors of prognosis in metastatic breast cancer: clinical application outside a clinical trial

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### ABSTRACT

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**Aims and background.** Circulating tumor cells have a prognostic role in metastatic breast cancer. The aim of the study was to confirm the ability of circulating tumor cells, detected by the US Food and Drug Administration approved Cell Search assay, to predict the outcome of patients treated in a community general hospital.

**Patients and methods.** A prospective mono-institutional study was conducted at the Department of Medical Oncology at Spedali Civili, Brescia, Italy, from January 2009 to September 2010. A total of 93 consecutive patients with metastatic breast cancer were enrolled. Patients underwent a blood sample collection to detect circulating tumor cells at baseline and, subsequently, at the first follow-up examination (after 3-4 weeks from the beginning of a systemic therapy). A third sample was drawn at disease progression (at the beginning of a subsequent new course of therapy). The prognostic cutoff value of circulating tumor cells was fixed at 5 cells/7.5 ml of blood.

**Results.** At baseline, median overall survival and progression-free survival in the subgroup  $\geq 5$  circulating tumor cells/7.5 ml of blood were significantly shorter (5 months and 3 months, respectively) than in the subgroup with  $< 5$  circulating tumor cells (8 months and 7 months, respectively) ( $P = 0.003$  and  $P < 0.001$ ). At the first follow-up, the subgroup with more than 5 circulating tumor cells/7.5 ml of blood had a median overall survival of 4 months *versus* 8 months in the subgroup with  $< 5$  circulating tumor cells ( $P < 0.001$ ) and a median progression-free survival of 3 months *versus* 7 months respectively ( $P < 0.001$ ). At multivariate analysis, the level of circulating tumor cells at the first follow-up and at baseline remained significant as a predictor of progression-free and overall survival. The number of metastatic sites was significantly associated with overall and progression-free survival and correlated with the number of circulating tumor cells.

**Conclusions.** Our study confirms the role of circulating tumor cells as predictors of prognosis in metastatic breast cancer patients treated in general clinical practice.

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**Key words:** breast cancer, circulating tumor cell, metastasis.

*Disclosure statement:* The authors have no conflicts of interest.

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Received March 21, 2011;  
accepted June 26, 2011.