

Associations of circulating tumor cells with outcome in patients with her2-negative metastatic breast cancer treated with eribulin – results from the phase ii detect ivb trial

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Abstract

Background: Eribulin is a non-taxane microtubule inhibitor that showed a survival benefit in pretreated metastatic breast cancer (MBC) patients. Circulating tumor cells (CTCs) are a known prognostic marker, but their role in predicting response to specific MBC treatments is less clear.

Objective: Here we report associations of CTCs at baseline and at first follow-up with clinical outcome in high-risk MBC patients treated with eribulin in the clinical phase II trial DETECT IVb.

Patients and Methods: Patients with HER2-negative MBC were screened for CTCs within the DETECT study program using the CellSearch® technology (Menarini Silicon Biosystems; Bologna, Italy). CTC-positive patients with exclusively HER2-negative CTCs and either triple-negative tumors or hormone receptor-positive tumors with an indication for chemotherapy were eligible for the single-arm DETECT IVb study and received single-agent chemotherapy with eribulin (HALAVEN®). The primary endpoint was progression-free survival (PFS), and secondary endpoints included overall survival (OS) and CTC clearance rate.

Results: The Median PFS and OS for the 109 included patients were 4.6 months and 13.4 months, respectively. Patients with five or more CTCs at baseline had a significantly worse PFS (HR 1.63, 95% CI 1.02 – 2.62, $p = 0.043$) and OS (HR 2.25, 95% CI 1.36 - 3.74, $p = 0.002$) than those with 1-4 CTCs. Complete CTC-clearance at first follow-up could be achieved in 26 (34.7%) of 75 patients with available follow-up CTC assessment (median 33 days after registration). Patients with complete CTC clearance at first follow-up had numerically but not significantly improved PFS and OS compared to patients with at least one CTC at first follow-up. Patients with less than 5 CTCs at first follow-up had significantly better PFS (median 4.9 vs 2.8 months; HR 0.45, 95% CI 0.25 – 0.81, $p = 0.006$) and OS (median 15.0 vs 10.5 months; HR 0.53; 95% CI 0.31 – 0.92, $p = 0.023$) than patients with 5 or more CTCs.

Conclusion: Our data confirm the role of CTCs as prognostic marker in MBC and showed possible clinical utility as a tool for monitoring therapy response to eribulin treatment.

Do you have any conflicts of interest?

Yes, I have a conflict of interest.

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