

DIAGNOSIS DEFINED

CTC
Metastatic Breast Cancer
Case Study 2

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Circulating Tumor Cell (CTC) Test

Key Benefit of Using the CTC Test

- Elevated CTC count provided an early indicator that patient's prognosis remained poor.
- Reduction in CTC levels, along with stable imaging results provided confidence that the patient could be moved to a less toxic therapy.

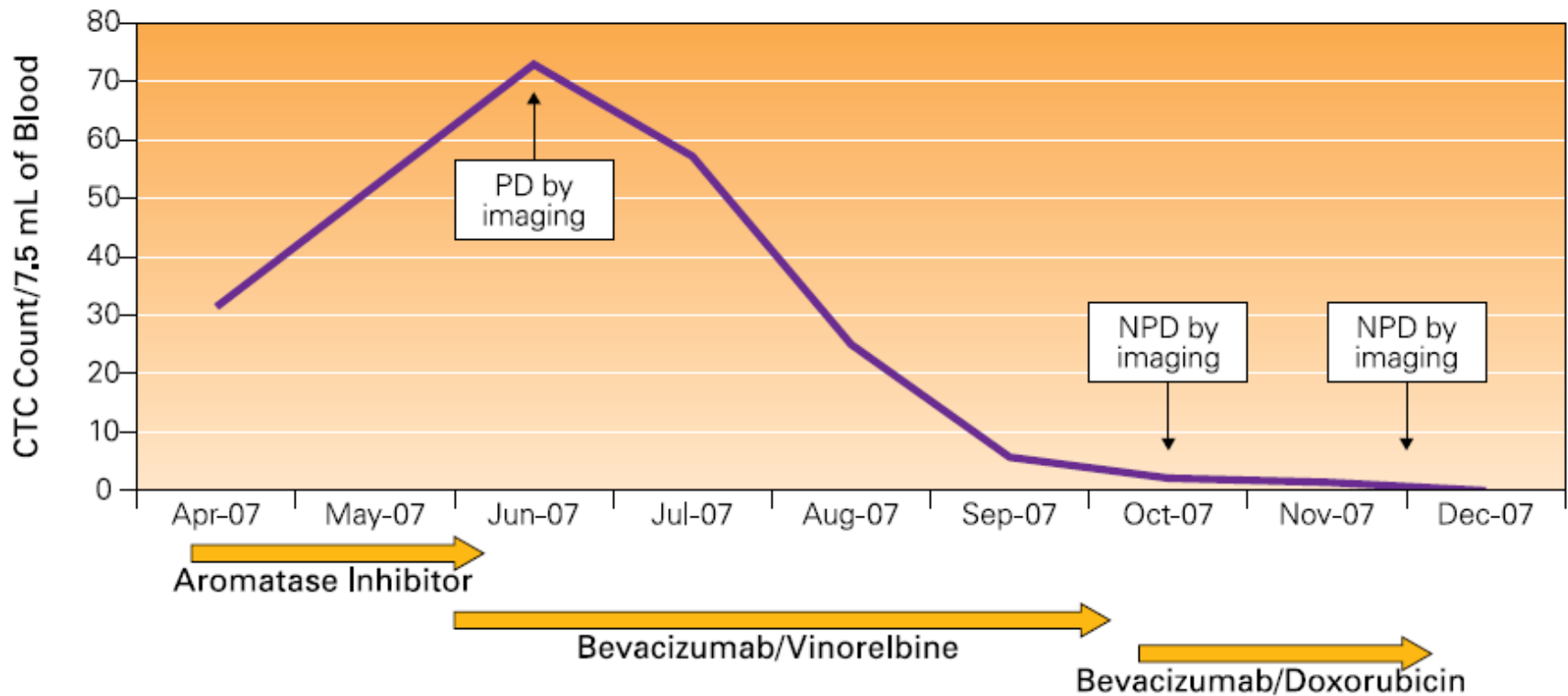
Patient Information

- Age: 39
- Diagnosis: Metastatic Breast Cancer (MBC)
- Line of Therapy: 3rd
- Current Therapy: Bevacizumab/doxorubicin
- Time with Metastasis: 10 months
- ER/PR & HER2 Status: ER positive/PR positive/HER2 negative
- Sites of Metastasis: Liver

Case Study Snapshot

- Patient wanted to pursue aromatase inhibitor therapy despite a baseline count of 32 CTC/7.5 mL of blood, and other non-favorable clinical factors.
- A CTC level of 74 after 6 weeks and correlated with progressive disease as determined by imaging.
- Patient was convinced to move to a chemotherapeutic regime to which she responded.
- Subsequent monitoring of this patient by imaging and CTC analysis showed no evidence of progression and the patient was eventually switched to a less toxic therapy.

Patient Longitudinal Graph



PD-Progressive Disease by imaging, NPD-Non-Progressive Disease by PET/CT.
The clinical cutoff of CTC per 7.5 mL of blood for MBC patients is ≥ 5 .

Background on the Patient

- Patient presented with a large T2 (4.5 cm), N2 grade 3 infiltrating ductal carcinoma with 6 of 24 positive axillary lymph nodes in May of 2002.
- At her 5-year visit in the spring of 2007, after 49 months of hormonal therapy, she presented with a single organ liver metastases.

Background on the Patient

- I ran the CTC test to determine a baseline reading.
- Her count of 32 CTC/7.5 mL of blood was elevated above the clinical cutoff of 5.
- Despite a recommendation of chemotherapy with bevacizumab for this visceral crisis, the patient instead wished to pursue a strategy of radical estrogen lowering with an aromatase inhibitor and multiple complementary therapies with a combined goal of lowering total body estradiol.

Background on the Patient

- Patient and I agreed that we would conduct an early reassessment of this strategy by both imaging (MRI) and CTC.
- Both of these diagnostic tools showed progression 6 weeks later.
- The CTC were 74, which put her in a poor prognostic category and this finding was helpful in convincing the patient to accept other treatment.

Background on the Patient

- On a new treatment, patient had an excellent response from the bevacizumab/vinorelbine therapy as reflected by MRI and by her decreasing CTC counts.
- Her CTC count eventually dropped to zero and this provided us additional confidence to place her on doxorubicin for a lower side effect profile.

Background on the Patient

- With this patient, I have used CellSearch™ at recurrence to determine her prognosis at baseline. Her elevated CTC levels coupled with diffuse liver metastases alerted me to this patient's poor prognosis very early on in her treatment.
- I was able to use this information to convince her to abandon an ineffective hormonal approach to treatment.

Value of CTC in the Treatment of this MBC Patient

- Initially the elevated CTC count in patient demonstrated she was in a high-risk state.
- Along with imaging, CTC testing supported a non-response to the initial change in hormonal therapy after 6 weeks.
- Her drop in CTC over the following months demonstrated an improved prognosis on this new line of therapy and provided confidence that we could move her to a less toxic therapy.

For *In Vitro* Diagnostic Use

- The Circulating Tumor Cell test is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood.
- The presence of CTC in the peripheral blood, as detected by the CellSearch™ Circulating Tumor Cell test, is associated with decreased progression-free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate cancer.

For *In Vitro* Diagnostic Use

- For further information on intended use, warnings, and limitations, please refer to the CellSearch™ CTC Test Instructions for Use, or visit www.veridex.com.
- CTC results should be used in conjunction with all clinical information derived from diagnostic test (e.g., imaging or laboratory tests), physical examination and complete medical history, in accordance with appropriate management procedures.

For *In Vitro* Diagnostic Use

- This case study is for educational purposes only and does not constitute professional medical advice.
 - The information provided in this case study should not be relied upon as the basis for making patient management decisions.
 - This case study is not intended to show that any line of therapy is any more or less effective than any other or no therapy.
- * The content for this presentation was provided by Veridex, LLC a Johnson & Johnson company

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