

**DIAGNOSIS DEFINED**

**CTC**  
**Metastatic Prostate Cancer**  
**Case Study 1**

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# Circulating Tumor Cell (CTC) Test

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## Key Benefit of Using the CTC Test

- CTC seemed to more rapidly change than prostate specific antigen (PSA); allowing earlier determination of the prognosis of this patient during chemotherapy treatment.

## MPC Definition

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Metastatic prostate cancer patients in this study were defined as having two consecutive increases in the serum marker PSA above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.

## Patient Information

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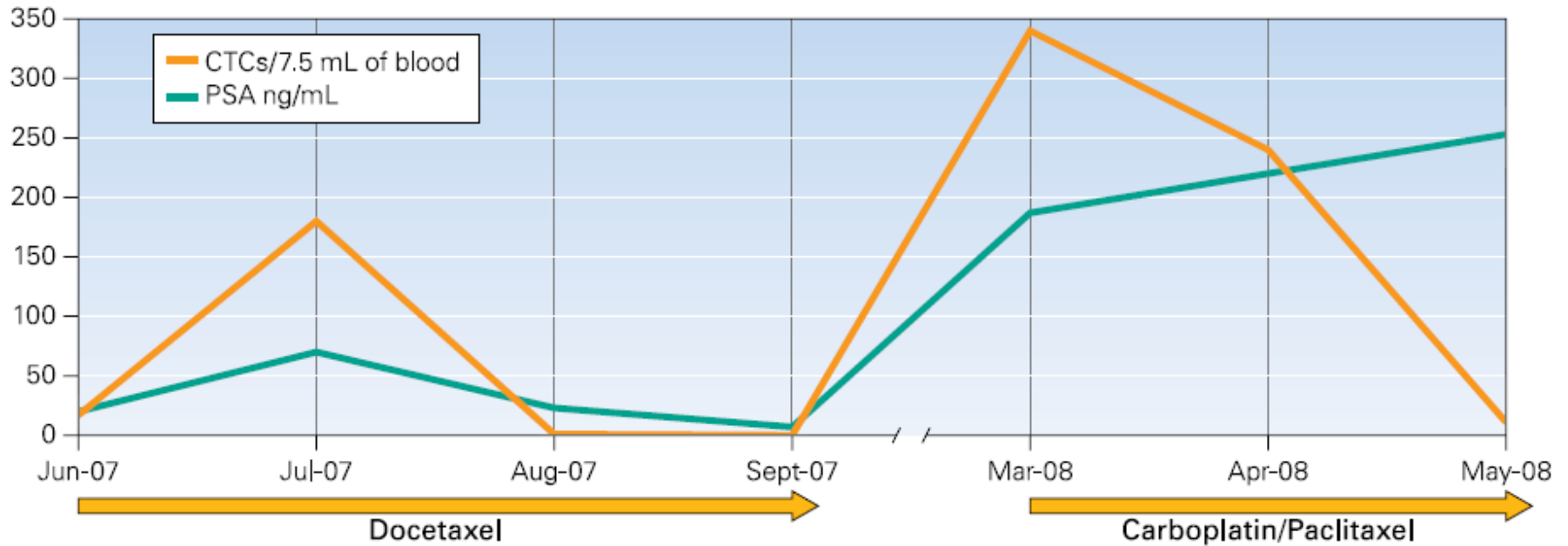
- Age: 73
- Diagnosis: Metastatic Prostate Cancer (MPC)
- Line of Therapy: 2nd line chemotherapy
- Current Therapy: Weekly carboplatin and paclitaxel
- Time with Metastasis: 1 year
- ECOG Score: 2
- Gleason Score: 10
- Sites of Metastasis: Bone, bulky pelvic lymphadenopathy

# Case Study Snapshot

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- Newly diagnosed prostate cancer transforms from hormone sensitive to hormone refractory.
- PSA and CTC levels predict recurrence of clinical symptoms.
- CTC counts appeared to change more rapidly than PSA allowing earlier prediction of progression-free survival and prognosis in this patient.

# Patient Longitudinal Graph



The clinical cutoff of CTC per 7.5 mL of blood for MPC patients is  $\geq 5$ .

# Background on the Patient

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- Patient presented in December 2006 with a hospitalization due to a left lower extremity deep vein thrombosis caused by newly discovered bulky pelvic lymphadenopathy.
- Initial staging CT scans also showed widespread bone metastasis.
- Initial PSA was 581 ng/mL and transrectal biopsy confirmed high-grade adenocarcinoma of prostate.

# Background on the Patient

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- Hormonal therapy was started with lupron intramuscular depot, oral casodex, and bone metastasis was treated with monthly intravenous Zometa.
- He had a clinical response manifested by a rapid reduction of bone pain.
- In February 2007, PSA nadir was 2 ng/mL.
- His tumor remained sensitive until June 2007, at which time PSA rose to 20 ng/mL.

# Background on the Patient

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- Suspecting the patient had become refractory to hormonal therapy a CTC test was ordered, and the first CTC result was 13, which is above the MPC cutoff ( $\geq 5$  CTC/7.5 mL blood) indicating poor prognosis.
- Since the patient had minimal tumor symptoms, he initially declined chemotherapy.
- In July, his PSA increased to 70 ng/mL, with a CTC of 180.

# Background on the Patient

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- Bone pain symptoms rapidly recurred, and he required a second hospitalization for pain control.
- He was treated emergently with rescue steroids and intravenous narcotics for bone pain and docetaxel chemotherapy was initiated.
- The first cycle of docetaxel induced cytoreduction of tumor burden with a decline of PSA to 23 ng/mL with a CTC of 1 per 7.5 mL of blood, which is below the MPC cutoff.
- An additional month of docetaxel led to a second PSA nadir of 7.1 ng/mL with a CTC count of 0.

# Background on the Patient

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- Unfortunately, in March 2008 his tumor rapidly relapsed.
- His PSA was 177 ng/mL, and he had a CTC count of 340/7.5 mL of blood.
- Second line chemotherapy salvage was started with weekly carboplatin/paclitaxel, and after 1 month his CTC count was 240.
- On May 14th his PSA was 253 ng/mL, but his CTC count had dropped to 11 per 7.5 mL of blood.

# Value of CTC in the Treatment of this MPC Patient

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- This case illustrated that the CTC count correlated with PSA.
- Furthermore, CTC seemed to more accurately reflect time points of tumor nadir response (CTC=1), maintenance (CTC=0), and peak relapse (CTC=340).
- Circulating tumor cells are a marker of hematogenous occult micrometastasis and provide real-time information on patient prognosis.

# Value of CTC in the Treatment of this MPC Patient

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- Comparatively, PSA is an indirect measurement of shed antigen reflective of overall systemic tumor burden, but may not be as sensitive at delineating active growth or regression during chemotherapy as was noted in this case.
- It was also noted in this case that both PSA and CTC were equally predictive of the onset of clinical symptoms

## For *In Vitro* Diagnostic Use

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- 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

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- For further information on intended use, warnings, and limitations, please refer to the CellSearch™ CTC Test Instructions for Use, or visit [www.veridex.com](http://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

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- 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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