Circulating Tumor Cell (CTC) number has been shown to be prognostic for survival pre- and post-therapy for use as an aid to monitoring breast, colorectal and prostate cancers. Historically, CTCs are counted as any cell in 7.5 mL of blood that is captured by EpCam, is CD45-, and expresses cytokeratin’s (CK)1.

Here we report the prognostic significance of CTCs detected using the enrichment-free EPIC Sciences platform in mCRPC patients prior to treatment with an AR signaling inhibitor. CTC were counted from 3 mL of blood for this analysis and defined as any CK+, CD45- cell with an intact DAPI+ nucleus.

The association of CTCs number with overall survival and time on drug in univariate and multivariable Cox PH modeling.

**Background**

- Circulating Tumor Cell (CTC) number has been shown to be prognostic for survival pre- and post-therapy for use as an aid to monitoring breast, colorectal and prostate cancers.
- Historically, CTCs are counted as any cell in 7.5 mL of blood that is captured by EpCam, is CD45-, and expresses cytokeratin’s (CK)1.
- Here we report the prognostic significance of CTCs detected using the enrichment-free EPIC Sciences platform in metastatic castration-resistant prostate cancer (mCRPC) patients prior to treatment with an AR signaling inhibitor. CTCs were counted from 3 mL of blood for this analysis and defined as any CK+, CD45-, cell with an intact DAPI+ nucleus.

**Methods**

Patient flow diagram for samples included for analysis:

- The Epic Sciences CTC Detection Platform
- Circulating Tumor Cell Definition
  - Has epithelial lineage (CK+)
  - No leukocyte lineage (CD45-)
  - Has an intact nucleus (DAPI+)
  - Clusters of CTCs are counted as 1 event
  - The reported CTC number is from or per 3 mL of blood
  - Median turnaround-time is 4 days from blood collection

**Results**

- CTCs were detected in >90% of mCRPC patient blood samples in the 1st, 2nd, and 3rd line settings prior to initiation of an AR signaling inhibitor (ARSi).
- The association of CTCs number with overall survival and time on drug in univariate and multivariable Cox PH modeling:
  - CTC Number Considered as a Continuous Variable Had the Highest AUC for event. CTC number is the number of CTCs detected in the 3 mL of blood analyzed.
  - The “o” refers to censored events, while the “x” indicates a death.
  - Solid lines indicate the estimated median survival times using a gaussian kernel density estimate.
  - Kaplan-Meier analysis of CTC-

**Conclusions**

1. >90% of blood samples from 1st-3rd line mCRPC patients taken prior to starting an Androgen Receptor Signaling inhibitor contained detectable CTCs (CK+, CD45- negative cells) in the 3 mL analyzed.
2. CTCs detected on the EPIC Sciences platform are prognostic in mCRPC patients about to start an Androgen Receptor Signaling inhibitor (ARSi).
3. Patients with low CTCs had longer time on an ARSi, suggesting that CTC counts determined on the EPIC Sciences platform could be used to identify patients more likely to have greater benefit.
4. The results warrant prospective testing of CTC counts on the EPIC Sciences platform as a baseline prognostic tool as ongoing studies evaluate the CTC count biomarker as a response monitoring tool.

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