Smart biosurface® technology for prostate cancer detection and risk stratification through ctc enumeration and biomarker expression profiling

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Abstract

BACKGROUND

Prostate cancer (PCa) is one of the most prevalent cancers in men and a significant cause of cancer-related deaths. The gold standard for PCa detection and risk classification includes Prostate-Specific Antigen (PSA) testing, digital rectal examination, and tissue biopsy. However, blood-based liquid biopsy offers a non-invasive alternative for analyzing tumor cell derivatives in the bloodstream, providing molecular insights and prognostic value.

OBJECTIVE

Our study evaluates the use of SmartBioSurface® (SBS) Technology in patients undergoing biopsy for suspected PCa, focusing on its effectiveness in identifying clinically significant disease (Gleason Score ≥7 or Gleason Grade group ≥2 according to European Association of Urology Guidelines).

METHODS

We developed a novel method to identify and characterize circulating tumor cells (CTCs) using SBS® technology and prostate-specific biomarker staining. CTCs and clusters were detected via immunofluorescence, targeting Prostate-Specific Membrane Antigen (PSMA), Prostate-Specific Antigen (PSA), Androgen Receptor (AR), epithelial (panPK/EpCAM), and hematopoietic (CD45/CD66b) markers.

RESULTS

The study included 60 men undergoing prostate biopsy: 15 with benign prostatic hyperplasia (BPH), 13 with low-risk disease (LR), and 24 with clinically significant disease (CSD), along with 8 healthy donors (HD) as controls. The SBS technology identified an average of 1.41 CTCs (defined as prostate marker and/or epithelial marker positive and hematopoietic marker negative) (Standard Deviation, SD: 1.56) in healthy donors, 2.53 (SD: 1.73) in low-risk patients, and 6.41 (SD: 5.11) in CSD patients. Preliminary results indicate that PSA, PSMA, and AR are informative biomarkers for detecting CTCs (single cells and clusters). A statistically significant difference ($p<0.05$) was observed between the CSD and LR groups, while no significant differences were observed between the LR and the BPH cohort ($p>0.6$). Under the most stringent conditions, a 3.41 CTC/ml threshold distinguished HD from CSD, achieving 100% specificity and 59% sensitivity.

CONCLUSION

This pilot study using SmartBioSurface® technology suggests a potential correlation between CTCs and tumor presence. Our technology was also able to stratify patients with clinically significant disease from those with insignificant cancer. These findings support the potential for larger clinical studies to determine whether CTC enumeration can provide more precise diagnostics than standard practices for accurately detecting tumors and assessing disease severity.

Do you have any conflicts of interest?

Yes, I have a conflict of interest.

Employee and shareholder of Tethis S.p.A