DNA methylation assay for diagnosis and screening of prostate cancer

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Technology description

Background

Prostatic adenocarcinoma is the most commonly diagnosed non-cutaneous cancer for men in the United States. The incidence is likely to continue to increase as people survive longer and more middle-aged men undergo routine screening for the disease. Men diagnosed with early stage small volume disease have the best outcome following curative treatment. Therefore the aim of early detection programs is to diagnose cancer at an early curable stage.

The current methodology involving diagnosis of prostate cancer (PCa) relies on the pathology examination of prostate needle biopsies, a method with high false negative rates partly due to temporospatial, molecular, and morphological heterogeneity of prostate adenocarcinoma. A great portion of men with tumor in prostate remain undiagnosed despite multiple biopsies. The problem that lowers the diagnostic rate of PCa is the heterogeneity of prostate tumor and its polymorphic representation across the prostate. It is postulated that molecular markers have a potential to assign diagnosis to a considerable portion of undetected prostate tumors.

Technology Overview

Lawson Health Research Institute researchers conducted a genome-wide DNA methylation analysis to investigate the DNA methylation changes in PCa using archival prostate cancer and normal tissues, and designed an algorithm that using methylation levels of probes which accurately classifies the prostate samples into benign or malignant. Approximately 6,000 probes and 500 genomic regions showed significant DNA methylation changes, primarily involving hypermethylation.

While others have proposed methylation and gene expression signatures to be used for diagnosis of prostate, none by far has been validated for clinical use. Using as few as four CpGs, our researchers trained a classification model with 100% accuracy in discriminating tumors from benign samples. Validation of this algorithm using an external cohort of 234 tumors and 92 benign samples yielded 96% sensitivity and 98% specificity.

Keywords

Cancer diagnosis, cancer/tumor profiling clinical detection, DNA methylation assay, epigenetics

Advantages

• Cheaper alternative to pathology examination for diagnosis of tumors
• New markers with high accuracy
• Prostate Cancer diagnosis
• Re-evaluation of tumor-suspicious samples (i.e. not positively detected in pathology examination)
• Confirm the existence of metastasis from prostate in other organs
• Detect metastatic lesions in bone, lymph node and soft tissue

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